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ahca

American Health Care Association

1201 L Street, NW, Washington, DC 20005-4014
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 2nd Main Fax: 202-289-4253
Writer's Telephone: 202-898-2828
Writer's E-Mail: hdaub@ahca.org
www.ahca.org

May 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-3818-P

2005 MAY -5 PM 4:32

***Re: Comments On Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities, Proposed Rule,* 70 Federal Register 6184, February 4, 2005, CMS-3818-P**

Dear Dr. McClellan:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule *Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities, Proposed Rule,* 70 Federal Register 6184, February 4, 2005, CMS-3818-P. AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical LTC. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

According to the Centers for Medicare and Medicaid Services (CMS), the existing requirements for dialysis facilities originally adopted in 1976 focus on a facility's *capacity* to furnish quality care rather than on the actual *provision* of quality care to patients and the outcomes of that care. In short, the existing end stage renal disease (ESRD) conditions do not require the facility to operate a patient centered, outcome-oriented quality assessment and performance improvement program. Thus, CMS expresses its commitment to modernize the existing regulations that are based on

largely procedural standards, and move toward a patient-centered outcome-based system that focuses on quality assessment and performance improvement.

AHCA understands CMS' goals and commitment regarding its revamping of the ESRD regulations. However, CMS has not proposed any regulations specifically addressing the provision of dialysis services in LTC facilities, nor has CMS indicated how it would try to achieve its goals and commitment to quality outcomes in this environment. Instead it has posed questions in the preamble to the proposed rule regarding the provision of dialysis services, in particular hemodialysis services, in LTC facilities within the model of home dialysis. CMS is asking whether the current home dialysis patient regulations need to be modified to protect the vulnerable LTC facility population and, if so, in what ways and under what particular circumstances.

AHCA's comments will focus on responding to the questions and issues that CMS raises with respect to the provision of dialysis services in skilled nursing facilities (SNFs) and nursing facilities (NFs), which we will refer to collectively as LTC facilities. It is AHCA's position that the home dialysis model is not appropriate for providing dialysis services in LTC facilities.

However, we wish to be able to provide dialysis when it is called for under a model appropriate for a LTC facility. There may be circumstances in which a LTC facility resident's medical condition and/or acuity precludes safe transporting to an ESRD facility for dialysis. If dialysis is indeed indicated, and a resident for medical reasons should absolutely not be transported to an ESRD facility -- then a way to serve that resident in the facility should be found. We understand that currently some LTC facilities are contiguous with an ESRD facility or have an ESRD facility located in the same physical structure as the LTC facility. In such situations, the resident does not have to be transported to a distant ESRD. This would appear to be the optimal situation to serve patients who should not be transported to distant ESRD facilities.

The ESRD proposed home dialysis regulation, at 42 CFR 494.100, addresses training of the patient or the caregiver, monitoring, and support services all appropriate to a home environment. It is clear that the proposed home dialysis regulations are not appropriate for a LTC facility environment. The home dialysis model ignores the acuity and frailty of the LTC resident population, the responsibilities and liability of LTC facilities which are highly regulated institutions providing care to a frail elderly population and held to strict standards in providing that care, and the necessity for reimbursement for all caregivers and nurses involved in the provision of dialysis in a LTC facility.

First, while caregivers may be substituted for the patient in a beneficiary's actual home under home dialysis rules, the home dialysis rules contemplate the potential that the patient can self-dialyze. Such potential does not exist in a LTC facility environment where it is not probable that any LTC facility resident would be able to self-dialyze. For example, approximately 48 percent and 3 percent of LTC patients

overall have some form of dementia or mental retardation, respectively.[1] In addition, 57 percent and 29 percent of LTC patients are not independently ambulatory or have contractures, respectively. Cognitive, physical impairment and normal decline prohibit the vast majority of LTC patients from providing self-care. Thus, if dialysis is to occur in a LTC facility, it must be performed by someone other than the resident.

Second, LTC facilities are highly regulated institutions providing care to a frail elderly population, and are held to strict standards in providing that care. Since the home dialysis rule is about dialysis performed in a private home, by its very nature it does not address the regulations and requirements governing LTC facilities and the relationship between these regulations and those governing ESRD facilities providing dialysis in LTC facilities.

Third, the issue of adequate reimbursement for all necessary staff is critical. In our detailed comments provided below, we discuss the staff that are necessary to provide dialysis services in LTC facilities and respond to CMS' questions regarding the role of nurses and other caregivers. A critical factor is that in the LTC facility environment there must be Medicare reimbursement for these services.

CMS has failed to demonstrate an appropriate basis for rulemaking regarding dialysis in LTC facilities.[2] CMS does not provide the data to support its assertion that "there is a potential growth for home dialysis in NFs and SNFs because of changing demographics in both the ESRD population and the general population." 70 Federal Register 6213. It must address the extent of the need for such services. CMS must provide the public and this profession with information regarding (1) the current demand for peritoneal and hemodialysis in LTC facilities as home dialysis and the degree to which they are now being performed in LTC facilities pursuant to CMS guidance, and (2) the changing demographics in both the ESRD population and the general population that indicate a potential growth for home dialysis in LTC facilities.

CMS must also address appropriate criteria for providing, in the LTC facility, dialysis to elderly LTC facility residents with chronic conditions. AHCA is supportive of providing the optimal environment for any given LTC facility resident

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[1] Computed by AHCA Reimbursement and Research Department using CMS OSCAR Nursing Facility database, December 2004.

[2] CMS cannot provide a final rule on the provision of dialysis services in LTC facilities simply in response to questions posed by CMS. Since questions alone cannot serve as a rational basis for a rule, any attempt to provide a final rule in this area would violate the requirements of notice and comment under the Administrative Procedure Act's standard of review, 5 U.S.C. §706. Further, before an agency finalizes a rule it "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made'." *Motor Vehicle Manufacturers Ass'n. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 at 42 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168, 83 S.Ct. 239, 9 L.Ed.2d 207 (1962)). CMS must provide a reasonable basis for regulation and a proposed regulatory framework.

to receive dialysis. However, the criteria driving the decision of providing dialysis, and the environment in which it is to be provided must include, in addition to medical necessity and quality of life, the choice of the safest possible environment for the given patient. An ESRD facility in most cases would be the safest and preferable site of service because it is set up specifically to provide dialysis services and thus must meet all conditions of coverage and participation for providing these services. Consideration should be given to reserving the option of services delivered in a LTC facility environment for those residents whose quality of life would clearly be improved by dialysis services but who should not be transported to an ESRD facility.

In sum, AHCA can support the provision of dialysis in LTC facilities if the conditions of coverage, the risks assumed by the facility, the relative roles of the LTC facility and ESRD facility, reimbursement, and other aspects of the service discussed below in our specific comments were clear and adequate to protect the resident, the LTC facility and the ESRD facility. CMS' regulatory and reimbursement framework must be adequate to support the highest possible quality for dialysis care.

We are calling for a thorough review of all the issues that should be considered in providing dialysis at the LTC facility site instead of an ESRD facility. We request that CMS work with the AHCA and the ESRD facility profession to develop appropriate conditions for coverage for the provision of dialysis services in LTC facilities. Only after such effort should CMS contemplate the issuance of a separate independent proposed rule on dialysis in LTC facilities.

We ask CMS to consider that perhaps there should be three models or categories of dialysis services: ESRD facility; home dialysis for those people residing in their own homes; and a third distinct category of dialysis services provided in LTC facilities. The LTC facility model should clearly delineate:

- LTC facility and ESRD responsibility for standards and conditions of participation and coverage;
- Appropriate criteria to determine the residents who might qualify for dialysis provided in a LTC facility;
- Adequate staff to perform and oversee all critical functions; dialysis to be provided by professional caregivers who are in the employ of or an independent contractor of the LTC facility or the ESRD facility, however the appropriate model would indicate; and
- Adequate Medicare reimbursement for all necessary personnel, including nursing staff, technicians, and caregivers, for the provision of dialysis services in order to provide and sustain quality dialysis services.

In our specific comments below, we respond to CMS' questions and raise issues that CMS will have to address in the development of an appropriate delivery model and regulation. We wish to reiterate that we support the provision of dialysis in LTC

facilities when it is necessary for the care of a given patient and that patient cannot be transported to an ESRD facility.

We ask that CMS come together with the LTC facility profession and the ESRD facility profession to develop a model that represents the best possible approach to providing dialysis services in LTC facilities and provides adequate Medicare payment for both the LTC facilities and ESRD facilities in order to sustain the model.

I would gladly work with you on these issues and welcome discussion on the development of an appropriate model.

Sincerely,

Hal Daub
President and CEO

Specific Comments

I. Insufficient Guidance for Application of Home Dialysis to LTC Facilities

In the preamble CMS indicates that it tried, through survey guidance, to clarify certification requirements and coordination of care requirements for residents of LTC facilities that receive ESRD services under a home dialysis model and to thus delineate the relative responsibility of the ESRD facility and the LTC facility.[3] CMS failed in this attempt at clarification, primarily because home dialysis, as we explained above, is not the appropriate model for providing dialysis, whether peritoneal or hemodialysis, in a LTC facility environment. The lack of clarity in the survey guidance referred to by CMS in the preamble and the questions posed by CMS in the preamble indicate that a model specific to the actual home of a beneficiary is being inappropriately torqued to apply to LTC facilities.

While current March 19, 2004 guidance to surveyors for ESRD facility provision of dialysis in LTC facilities confuses the issue and appears to imply that the ESRD facility staff would actually provide the dialysis treatment, our understanding is that the ESRD facility merely trains the "caregiver" to provide the dialysis and is not on the premises while the dialysis is being provided.[4] Further, there is no Medicare reimbursement for the caregiver who under current rules would have to be paid by the family or the LTC facility or some third party payor.

A system, such as may be in existence now, that causes either the LTC facility itself or families to pay the caregiver for these services creates a precarious, uneven and inequitable implementation of what is purportedly a Medicare service. In addition, such a framework lacks viability in the current universe of scarce nursing resources at any level -- be it registered nurse, licensed practical nurse (LPN) or certified nursing assistant (CNA). As we have indicated above, an appropriate model for delivering dialysis care in a LTC facility must clearly delineate who actually provides the treatment, that the provider of the treatment is in the employ or an independent contractor of the LTC facility or the ESRD facility, and that there is Medicare reimbursement for the services of the caregiver. It must also provide a regulatory framework that addresses LTC facility responsibility and liability under the conditions for coverage that CMS is proposing for ESRD facilities but which cannot help but impact LTC facilities.

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[3] March 19, 2004 letter to State survey agency directors entitled, "Clarification of Certification Requirements and Coordination of Care for Residents of Long-term (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services" (Reference: S&C–04–24). See also addendum to the March 19, 2004 letter sent state survey agency directors and that included as an attachment follow-up questions and answers regarding the scope of the guidance and the responsibilities of the providers (Reference: S&C–04–37), July 8, 2004.

[4] Id.

II. LTC Facility Responsibility and Liability Under ESRD Conditions for Coverage

A. LTC Facility Responsibility and Regulatory Environment

There are additional serious issues at stake that must be addressed with respect to the provision of dialysis in LTC facilities that are not currently addressed in regulation or guidance. A LTC facility is an institution responsible for the care of residents. In this regard it is very different from the common understanding of the term "home." LTC facilities must meet an entire pantheon of regulations and are subject to numerous enforcement mechanisms. The LTC facility has ultimate responsibility for its residents and the services provided to those residents by facility staff or outside providers.

While CMS has issued proposed regulations governing ESRD facilities, including dialysis in the ESRD facility or home dialysis in homes and LTC facilities, it has ignored the fundamental issue of the extent to which these proposed regulations will *de facto* apply also to LTC facilities permitting or providing dialysis on their premises. By assuming a model of home dialysis, CMS ignores the ultimate impact on LTC facilities and their ultimate responsibility -- clinical and legal -- of operational issues such as infection control, water quality requirements, adequate treatment areas, heating and ventilation systems, contamination prevention, and even poor quality dialysis. It is also clear that the survey protocol for LTC facilities provided in the referenced March 19, 2004 guidance to state surveyors fails to address these critical issues.[5] While CMS may ignore these issues, the public and the courts will not.

Indeed, CMS states that "Consideration must be given as to whether home dialysis care provided in a NF or SNF must comply with all of the proposed conditions for coverage, except § 494.120, that governs special purpose dialysis facilities and the specification at § 494.180(d) that services must be provided on or contiguous with the premises." The question is unclear. CMS may be asking for comment on whether the ESRD facility alone must comply with all of the conditions of coverage -- as it would in an ESRD facility -- when it is providing dialysis in a LTC facility. However, the appropriate question is whether any or all of the conditions of participation should apply to the host LTC facility when dialysis is being provided in a LTC facility, and whether they will be considered by surveyors.

On December 22, 1987, the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Pub. L. 100-203 was enacted, which included extensive revisions to the Medicare and Medicaid statutory requirements for NFs. These revisions were based on the a report issued by the Institute of Medicare to study federal regulations concerning long term care facilities and recommend changes that might enhance the ability of the regulatory system to assure that residents receive satisfactory care. The

[5] Id

recommendations were comprehensive, and the ensuing regulations addressed a broad spectrum of issues including resident rights, admission transfer and discharge rights, resident behavior and facility practices, quality of life, resident assessment, quality of care, nursing services, dietary services, physician services, specialized rehabilitative services, dental services, pharmacy services, infection control, physical environment, and administration. In addition to the regulations, there is extensive guidance to surveyors and strict enforcement of compliance, which includes penalties addressing degrees of deficiency.

The core OBRA '87 mandate is that "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being in accordance with the comprehensive assessment and plan of care." 42 CFR §483.25.

Further, the responsibility of the LTC facility does not stop at services provided by the facility -- it embraces all services provided to the residents, including those of outside contractors. With respect to outside resources, the facility is responsible both for "obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility" and "the timeliness of the services."[6]

At a bare minimum, in order to protect the residents, LTC facilities having dialysis units will need to become knowledgeable regarding the ESRD regulations and compliance in order determine the quality of the dialysis contractor providing the service, and whether the contractor ESRD facility is adhering to these regulations. However, it is clear that CMS must clarify the interaction, application, and relationship of the ESRD facility requirements and the LTC facility requirements. The following are just a few examples of areas of concern:

- ***Infection Control***

As stated above, LTC facilities have their own infection control regulations and extensive guidance. See 42 CFR 483.65. However, the proposed ESRD rule provides detailed requirements for infection control in a dialysis environment. CMS clearly states that patients with ESRD have impaired immunological systems and are

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[6] 42 CFR 483.75(h) mandates the following:
(h) Use of outside resources:
(1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph (h)(2) of this section.
(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for --
(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and
(ii) The timeliness of the services.

more at risk of developing serious infections than similarly-situated non-ESRD patients. CMS explains that during hemodialysis therapy, there is a potential for patients to be exposed to a variety of microbial pathogens (including blood-borne pathogens) if proper procedures are not meticulously followed. Likewise, peritoneal dialysis patients are at risk of contamination leading to peritonitis if proper procedures are not followed. CMS concludes that infection control is vital to the health and safety of dialysis patients and others and therefore is proposing infection control as a separate condition for coverage (42 CFR §494.30).

Thus, the proposed ESRD rule stipulates that the dialysis facility must provide and monitor conditions to ensure a sanitary environment that prevents the transmission of infectious agents within and between the unit and adjacent hospital or other public area. The ESRD facility must demonstrate that it follows standard infection control precautions by implementing -- (1) The "Recommended Infection Control Practices for Hemodialysis Units at a Glance," with the exception of screening for Hepatitis C, found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients' Morbidity and Mortality Weekly Report," volume 50, number RR05, April 27, 2001, pages 20 and 21, developed by the Centers for Disease Control and Prevention, and (2) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and by maintaining procedures, in accordance with applicable state and local laws and accepted public health procedures, for the handling, storage, and disposal of potentially infectious waste; and cleaning and disinfection of contaminated surfaces, medical devices, and equipment. While the proposed rules are directed to the actions of the ESRD facility staff or the designated caregiver, it is not clear in reality where the responsibility of the ESRD staff and caregiver and the LTC facility staff begins and ends -- since both have a responsibility for infection control.

CMS further proposes that "facilities must designate a registered nurse as the infection control or safety officer who maintains current infection control information, and reports to the facility chief executive officer or administrator and quality improvement committee. The infection control nurse must maintain current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication." (70 Federal Register 6193, 42 CFR §494.30 (b)). Most LTC facilities do not have full-time infection control nurses. Infection control duties are the responsibility of professional staff to complete with their regular patient care responsibilities or supervisory responsibilities. Current LTC infection control is mainly focused on the issues common to the care of and prevention of infection in chronic elderly patients. CMS would have to clarify how the LTC facility infection control responsibilities and the dialysis care infection control responsibilties interact. It may be that caring for dialysis patients in a LTC facility setting will require LTC facility employee training on the special infection control concerns of dialysis patients, use of personal protective equipment (like gloves), waste disposal, reuse and cleaning of nondisposable equipment, medication management, maintenance of clean areas, management of patient equipment, setting and adhering to Hepatitis B vaccination

schedules and coordinating lab tests, development of facility-specific performance measures and care standards, and infection control monitoring and reporting.

- ***Physical Environment and Emergency Preparedness***

Both LTC facility regulations and ESRD facility regulations provide requirements regarding the physical plant and environment.

In the proposed ESRD regulations, at 42 CFR §494.60, CMS provides requirements pertaining to the physical environment for dialysis care and for emergency procedures. CMS addresses the safety of the building; the maintenance of all emergency equipment, dialysis machines, and the water and treatment system, and the sufficiency of the space to provide dialysis.

In the emergency preparedness standard, proposed 42 CFR §494.60(d), CMS has proposed requirements that it believes are fundamental for a dialysis facility to prepare effectively for emergency situations. These requirements include: (1) procedures for medical and non-medical emergencies; (2) staff and patient training; (3) facility emergency equipment; and (4) periodic evaluation of emergency plans. CMS proposes to clarify at 42 CFR § 494.60(d) that each dialysis facility must implement emergency preparedness procedures to manage potential medical and nonmedical emergencies that are likely to threaten the health or safety of facility patients, the staff, and the public.

CMS explains that these emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The facility will need to identify which hazards are most likely to affect the facility, evaluate how to minimize risks, and plan how to best protect patients in the event of an emergency, using an emergency management approach. All facilities must plan for fire, care related emergencies, equipment and power failures, and interruption of the water supply, because these emergencies may occur regardless of a facility's geographic location.

LTC facilities also must comply with physical environment issues pertaining to the design and equipment of resident rooms, space and equipment, the safety of the physical environment, and life safety and emergency issues such as safety from fire and emergency power. See 42 CFR 483.70. Again, the regulations are further explicated in survey guidance on physical environment.

CMS' proposed rule raises the question as to what ESRD regulations will impact LTC facilities and, for example, what special consideration is needed on the part of LTC facilities for dialysis patients and dialysis equipment if, for example, emergency evacuation is needed. In sum, CMS must address the interface and relationship of ESRD facility regulation and LTC facility regulations. We believe that this is best

addressed in a separate regulation specifying which requirements apply to LTC facilities.

B. LTC Facility Legal Liability

In addition to meeting the LTC conditions of coverage and participation (and being subject to sanctions for failing to meet the requite standards), LTC facilities also are at risk for allegations of resident abuse and neglect with both criminal and civil penalties and negligence claims potentially leading to civil liability. The presence of dialyzing patients -- the care of the patients themselves and the bloodborne disease exposure for other residents -- increases this risk and exposure. In addition, agreeing to provide such services may substantially increase a LTC facility's professional liability costs. Thus, it is imperative that CMS provide clear regulations governing the provision of dialysis in LTC facilities delineating all LTC facility responsibilities for conditions of coverage that may overlap with those of the ESRD facility. It will also be imperative for LTC facilities to understand the overall risk of undertaking and providing such services.

III. Staffing Issues Raised By CMS

CMS poses several questions regarding staffing, including questions pertaining to the presence of a registered nurse during dialysis, the duties of this nurse, and patient to caregiver ratios. CMS also raises issues regarding training of staff and monitoring the care of the LTC facility resident. Again, the questions presume a home dialysis model with no Medicare reimbursement for the registered nurses. While we challenge the applicability of the home dialysis model, we nevertheless can respond to questions which address the need and role of registered nurses -- the presence of which we believe is crucial in any delivery model.

- ***Need For the Presence of A Registered Nurse***

CMS explains that the existing regulations (42 CFR §405.2162(b)) require that a licensed health professional (for example, physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care whenever patients are being dialyzed. This proposed rule, at 42 CFR §494.180(b)(2), would require that a registered nurse be on the premises whenever in-center patients are being treated. CMS believes that there would be a comparable risk to patient health and safety if a licensed nurse were not on the premises of the LTC facility and available during multiple simultaneous LTC facility dialysis treatments. CMS asks that consideration be given as to whether this registered nurse could be a NF or SNF registered nurse trained by the ESRD facility, or a registered nurse provided by the ESRD facility to be available during NF or SNF hemodialysis treatments. 70 Federal Register 6214.

AHCA firmly agrees that there is a high risk to patient health and safety if a licensed nurse were not on the premises of the LTC facility and available during multiple

simultaneous LTC facility dialysis treatments. A registered nurse should be present during dialysis, whether it is a LTC facility registered nurse trained by the ESRD facility, or a registered nurse provided by the ESRD facility. The registered nurse should be experienced and adequately trained to provide and to supervise dialysis services.

- ***The Duties of the Registered Nurse***

CMS also indicates that if the LTC facility were allowed to make this registered nurse available during hemodialysis treatments, the implications for care (requiring registered nurse attention) provided to other NF or SNF residents must be considered. CMS is considering and asks whether a limitation of the LTC facility registered nurse's duties is necessary, so that the nurse is available to meet dialysis needs while another nurse tends to the LTC residents (for example, such as the absence of direct LTC facility resident care responsibilities and allowance of only administrative duties). Id. It is AHCA's position that the registered nurse should be dedicated exclusively to the dialysis service duties and bear no additional responsibility for other LTC residents.

- ***Training***

CMS believes that training provided by the certified ESRD facility should be specified and the ESRD facility should be responsible for providing training to the LTC facility staff and to all caregivers who will be working with the ESRD patients. These caregivers could possibly include the nursing and support staff of the residential institution, dialysis facility nurses and patient care technicians, and the caretaker that may be provided by the durable medical equipment (DME) supplier, if available and the patient is a Method II home dialysis patient. CMS notes that Medicare does not provide additional reimbursement for caregiver services within the current payment system. CMS believes that caregiver-training requirements that are similar to the training specifications for home dialysis patients may be appropriate.

AHCA's position is that training provided by the certified ESRD facility should be specified and the ESRD facility should be responsible for providing training to the LTC facility staff and to all caregivers who will be working with the ESRD patients. These caregivers could possibly include the nursing and support staff of the residential institution, dialysis facility nurses, and patient care technicians.

We believe that the caregivers should be in the employ of or independent contractors of either the LTC facility or the ESRD facility and that Medicare reimbursement be provided for the caregiver services. Thus, caregivers should not be family members if they are not trained dialysis providers and in the employ or independent contractors of either the LTC facility or the ESRD facility. Further, AHCA disagrees with CMS' statement that the training provided to caregivers in the home would be appropriate for caregivers in the LTC facility. In response to CMS, AHCA

believes that caregiver-training requirements that are similar to the training specifications for home dialysis patients are neither relevant nor applicable in LTC facilities. Rather, the caregiver-training requirements in LTC facilities should be identical to those of caregiver or technicians who provide dialysis in ESRD facilities.

In this regard CMS solicits comment on what competency requirements and experience/qualifications should be proposed for the caregiver and for the registered nurse, what restrictions should be placed on the caregiver or the registered nurse or both. AHCA recommends that the competency requirements and experience qualifications for the caregiver and for the registered nurse be the same as those for their counterparts in the ESRD facilities.

- ***Caregiver Ratios***

According to CMS, in a typical home dialysis patient situation, the ratio of patient to caregiver is one-to-one. CMS solicit comments on whether CMS should address patient to caregiver ratios in a situation when the LTC facility is considered the patient's residence. As stated above, AHCA does not believe that home dialysis is the appropriate model for dialysis services in LTC facilities, and that therefore the LTC facility should not be considered the patient's residence for the purpose of home dialysis services. The development of an appropriate model for dialysis services in LTC facilities will drive the appropriate ratio.

IV. Additional Staff Issues

- ***Recommended Additions To LTC Facility Staff***

We take this opportunity to recommend additions to LTC facility staff that we believe will ultimately be needed for provision of quality dialysis care: a dedicated dialysis facility nurse; an infection control nurse; and an advanced practice nurse (APN), such as a geriatric nurse practitioner. The APN should be facility-based and involved in the following:

  - Providing medical oversight on a daily basis when the medical director and treating physician are not physically at the facility;
  - Coordinating care between the ESRD provider, facility, medical director, and treating physician;
  - Overseeing patient care during and after dialysis;
  - Providing a back-up when the facility-based, dedicated dialysis registered nurse is not available;
  - Training facilities staff on the care concerns of the dialysis patient;
  - Overseeing the development of a coordinated care plan;
  - Coordinating infection control activities, data collection, and reporting with the infection control registered nurse;
  - Addressing health and care concerns with the medical director, ESRD provider, and treating physician;

- Addressing ethical and moral concerns with the medical director, ESRD provider, and treating physician related to patient condition, progress, prognosis, and need for care plan changes; and
- Working with the medical director to establish recommendations and procedures associated with the use of an automatic external defibrillator.

- ***The Role of the LTC Facility Medical Director***

The regulations governing LTC facilities, at 43 CFR §483.75(i) require that the facility must designate a physician to serve as medical director who is responsible for the implementation of resident care policies and the coordination of medical care in the facility. We are aware that CMS will soon release a final version of revisions to the State Operations manual interpretive guidance and survey protocol for medical director requirements. These revisions will increase the involvement of the medical director in facilities' care practices and policies and will increase the expectations of facilities' use of their medical directors. In addition, the LTC facility resident may have his or own attending physician.

The proposed ESRD regulations also require a medical director to be a physician who has completed a board-approved training program in nephrology and who has at least 12 months of experience providing care to patients receiving dialysis. The medical director's responsibilities include, but are not limited to, the following:

- Quality assessment and performance improvement program.
- Staff education, training, and performance.
- Policies and procedures. The medical director must --
  - Participate in the development, periodic review, and approval of a "patient care policies and procedures manual" for the facility; and
  - Ensure that --
    - All policies and procedures relative to patient care and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and
    - The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in the regulations.

It is clear that the care of LTC residents who would be receiving dialysis would be impacted by the roles and responsibilities of three categories of physicians. An appropriate model for delivery of dialysis services in LTC facilities must acknowledge these roles and responsibilities and delineate communication between all three.

- ***Impact of the Current Nursing Shortage***

One major impediment to the development of an appropriate LTC facility dialysis service model is the current shortage of nurses which is expected to continue for several decades. Nearly 96,000 nurses and other health care professionals are needed to fill vacant positions in LTC facilities across the country. The projected increase in registered nurse employment in LTC facilities between 2000 and 2010 is 130,000.[7] In 2002, over 15 percent of registered nurse positions in LTC facilities were vacant, and the average rate of turnover for these registered nurses was 49 percent.[8] We suspect that ESRD facilities may face similar shortages in trying to staff their facilities, and that recruitment and retention of nursing staff has been and continues to be a major issue for all health care settings.

AHCA is undertaking enormous outreach and efforts to overcome the devastating impact of the nursing shortage and has taken an active role in improving the quality of the LTC workforce. For example, AHCA engaged George Washington University (GWU) to coordinate the creation of a national workgroup commission, called the National Commission on Nursing Workforce for Long Term Care. The national commission is a collaborative effort dedicated to LTC workforce problem solving. The commission encompasses representatives from LTC organizations, nursing education, labor, and advocates for elder care. A major purpose of this initiative is to create a successful collaborative model that can be utilized at the state and local levels to form partnerships in addressing caregiver recruitment and retention problems. The collaborative model eliminates the ineffective, one-size-fits-all approach and fosters stakeholder and problem solving flexibility sensitive to geographic variances in supply, demand, available care services, and education resources.

In addition, the National Foundation for the Advancement of Elder and Disabled Care in America, in collaboration with GWU, applied for and have been awarded a planning grant from the Department of Labor. The primary objective of the planning grant is to develop the infrastructure of Best Practice (Partnership) models than can be expanded, evaluated, replicated, and transported to other areas of the country.

We are continuing our efforts in this area. One vital factor in trying to cope with the nursing shortage and recruit nurses to provide dialysis services within an appropriate LTC facility model is adequate funding for these services, including Medicare reimbursement for all necessary staff.

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[7] See *The Future Supply of Long-Term Care Workers in Relation to the Aging Baby Boom Generation,* Report to Congress, U.S, Department of Health and Human Services, Washington, DC, May 14, 2003, p. 10.

[8] *Results of the 2002 AHCA Survey of Nursing Staff Vacancy and Turnover in Nursing Home,* American Health Care Association, February 12, 2003, p.5.

NxStage Medical, Inc.
439 South Union Street
5th Floor
Lawrence, MA 01843
Phone: 978-687-4700
Fax: 978-687-4800

May 5, 2005

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on CMS-3818-P (Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities)

Dear Dr. McClellan:

NxStage Medical, Inc. ("NxStage") appreciates this opportunity to comment on the above-captioned proposed rule, published in the Federal Register on February 4, 2005 (the "Rule"). 70 Fed. Reg. 6184. We are a medical device company that develops, manufactures and markets innovative systems for the treatment of end-stage renal disease ("ESRD"), acute kidney failure and fluid overload. Our comments are limited to the proposed changes to water quality requirements for hemodialysis set forth in proposed sections 494.40 and 494.100.[1]

Under the Proposed Rule, CMS recommends, and we agree, that water quality standards should meet the standards in the Association for the Advancement of Medical Instrumentation ("AAMI") document entitled "Water Treatment Equipment for Hemodialysis Applications," identified as RD62:2001. We disagree, however, that facilities must demonstrate their ability to meet these standards pursuant to certain AAMI monitoring requirements (incorporated by the Proposed Rule), where such monitoring would impose unnecessary burdens on dialysis facilities without yielding better water quality. Specifically, we request that CMS Conditions for Coverage exempt from such monitoring requirements preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water, and instead allow facilities to follow the monitoring requirements imposed by the Food and Drug Administration ("FDA") cleared labeling for such preconfigured systems.

We recently received clearance from FDA for such a system, and believe the imposition of further monitoring requirements, above what is already designed into our system or required by our system's FDA cleared labeling, would impose undue burden without any patient benefit. Importantly, we also believe our suggested change in the Proposed Rule is consistent with the spirit of the stated intent of the Proposed Rule – to empowerment of the dialysis facility medical director position as outlined in the proposed rule.

[1] The entirety of this comment letter is addressed to the caption topics "Water Quality" and "Care at Home" identified in the Proposed Rule.

reflect advances in dialysis technology and focus on patient outcomes of care and eliminating unnecessary procedural requirements.[2]

DISCUSSION

I. Different Means of Assuring Water Quality Should Be Permitted

A. The AAMI Standards for Water Quality Monitoring Are Directed at Systems Used in Facilities that Utilize Custom Configuration of Components.

We agree that all water used by dialysis patients should meet the AAMI standards for water quality incorporated by the Proposed Rule. We disagree that there should be only one way of demonstrating compliance with these water quality standards. In RD62:2001 (portions of which have been incorporated into the Proposed Rule), in explaining the scope of the standard, AAMI indicates that it "is written principally to address water treatment systems for dialysis facilities treating multiple patients."[3] Moreover, the current AAMI standard RD62:2001 was not drafted in a manner that takes into consideration newer technology incorporated into preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water (typically supplying a single patient). The AAMI standard referenced in the Proposed Rule is approaching four years since its approval, is biased towards older technologies used in dialysis facilities and serving multiple patients, and fails to account for this newer technology (several important commercial examples of which were cleared after 2001). Thus, we urge CMS to provide dialysis facilities with the flexibility to use means in addition to the AAMI standards to assure compliance with water quality standards, as discussed in Section II below.

B. There are Two Approaches to Water Treatment: One Using Custom Configured FDA Cleared Components (Typically Supplying Multiple Dialysis Machines), Another Using Preconfigured, 510(k) Cleared Systems Designed, Tested and Validated to Produce AAMI Quality Water (Typically Supplying a Single Patient).

Most dialysis patients are treated in dialysis facilities that use custom configured FDA cleared components to treat the water used to prepare dialysate. These systems typically supply multiple dialysis machines simultaneously. RD62:2001, Annex A section A.3 "Responsibility for compliance with the standard" recognizes this practice by stating: "[w]ater treatment and distribution systems incorporate a variety of devices. These devices may be provided and installed by different vendors, making it difficult to assign responsibility for compliance with this standard to any one individual or company." Once these systems are installed, facilities need to engage in monitoring of the system to ensure that the custom configured components, when assembled into a system, can provide and

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2 70 Fed. Reg. at 6185.

3 ANSI/AAMI RD62:2001, Section 1.1.

continue to provide water that meets the appropriate AAMI quality levels. For such systems, the AAMI monitoring standards incorporated by the Proposed Rule seem appropriate.

A much smaller subset of patients (likely less than one percent of all ESRD patients) rely upon preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water (typically single-patient systems). These systems may employ continuous monitoring (i.e., 100% verification) and protective measures to ensure patient safety, such as inclusion of an automatic shut off if quality parameters are not met. Importantly, such systems are FDA cleared and do not require additional monitoring to ensure AAMI water quality requirements are met, beyond what is designed into the systems or required by the systems' cleared labeling. There is no customization of components required or, indeed, allowed by the systems' design. Users of these systems can, therefore, be assured that the systems will perform as validated and FDA cleared, without further testing or monitoring required, beyond any required by FDA cleared labeling.

As stated above, AAMI's monitoring standards are appropriate for custom configured systems using one or more manufacturers' FDA cleared components that have not been FDA cleared and validated, as installed in their final configuration, to produce AAMI quality water. They are not appropriate for preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water. The Proposed Rule does not take into account these systems and we urge CMS to adopt the changes suggested in Section II to accommodate these systems.

C. Application of the AAMI Standards to Preconfigured, 510(k) Cleared Systems Designed, Tested and Validated to Produce AAMI Water Would Create Significant Additional Burdens and Costs for Facilities and Patients Without Any Related Benefit.

Preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are generally used in the home setting. We acknowledge that CMS appears to incorporate reduced AAMI monitoring requirements for water treatment systems used in patient homes. For both settings, CMS would incorporate water quality and monitoring requirements in RD62:2001, sections 4.2.1, 4.2.2, 5.2.1 and 5.2.2.[4] In proposed 42 C.F.R. § 494.40(a)(1)(iii) and (a)(2), CMS also would require additional specific steps be taken to ensure that the AAMI standards contained in the aforementioned sections are met, but seems to apply that only to systems in dialysis facilities. This is because the home dialysis requirements on water quality only reference proposed 42 C.F.R. § 494.40(a)(1)(i) and (ii), not subsections (a)(1)(iii) and (a)(2).[5] However, we believe even these reduced

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[4] 70 Fed. Reg. at 6247 (proposed 42 C.F.R. § 494.40(a)(1)(i) and (ii)). See also proposed 42 C.F.R. § 494.100(c)(1)(v).

[5] 70 Fed. Reg. at 6251 (proposed 42 C.F.R. § 494.100(c)(1)(v)). NxStage believes it is appropriate for there not to be a cross-reference to proposed 42 C.F.R. § 494.40(a)(1)(iii) or (a)(2) in the home dialysis water quality conditions because single-patient, preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are used in homes. However, since these systems also may be used in dialysis facilities, CMS must offer facilities the same flexibility with regard to this new technology that is offered in the home.

requirements impose unnecessary burdens and costs on home patients and their dialysis facilities. Whether preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are used in patient homes or dialysis facilities, no additional monitoring to ensure AAMI water quality standards are met should be required beyond that required by FDA cleared labeling for such systems.

Below we explain how the various AAMI standards in RD62:2001, included in proposed 42 C.F.R. § 494.40(a)(1)(i) and (ii), would impose added burdens on facilities using this type of system:

- *Section 4.2.1 requires that when action levels for bioburden or endotoxin are observed, corrective measures such as disinfection and retesting must occur. This Section further requires that the manufacturer or supplier of the water treatment system demonstrate at the time of installation that water quality requirements are met.*
    - With FDA cleared, preconfigured systems like ours, the pertinent components (i.e. dual ultrafilter assembly) would be replaced on a set schedule per the labeling such that other measures would be duplicative and/or unnecessary.
    - The requirement that testing be done at installation is also inappropriate for FDA cleared, preconfigured systems like ours that have already been validated to perform in any environment where they are installed, according to the cleared labeling. The requested testing would be time consuming, costly, and produce no discernible improvements in water quality.
- *Section 4.2.2 requires that the manufacturer or supplier must recommend a system that can meet the pertinent contaminant levels given an analysis of the feed water and seasonal variations in feed water.*
    - Our system and other FDA cleared, preconfigured systems like it, are validated and may employ continuous monitoring technology to meet the applicable levels regardless of the feed water such that a required analysis of the feed water would again be time consuming, costly and produce no discernable improvements in water quality.
- *Section 5.2.1 addresses the collection of samples to assess water bacteriology and is applicable to machines used by more than one patient.*
    - It is not relevant to systems like ours that are validated and labeled with a specific shelf-life after installation so as to not require water bacteriology sampling.
- *Section 5.2.2 discusses methods for testing water for chemical contaminants.*
    - It is not relevant to systems like ours that are validated and labeled with a specific shelf-life after installation so as to not require water chemical sampling.

Likewise, to the extent CMS' interpretation of the Proposed Rule is inconsistent with that set forth above, or in the event that preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are used in dialysis facilities, we believe that certain requirements in proposed 42 C.F.R. §§ 494.40(a)(2) and (a)(1)(iii) of the

Proposed Rule also would impose unnecessary burdens and costs and provide no further benefit to patients or assurance of water quality. Proposed 42 C.F.R. § 494.40(a)(2) would require monthly measuring of bacteria and bacterial endotoxin levels in established systems, with weekly measurements in newly installed systems mandated until a pattern of compliance can be shown. The monitoring must be done consistent with RD52: 2004, section 7.2.1.[6] Because systems like ours are FDA cleared, designed, tested and validated to produce AAMI quality water, and include continuous monitoring with an automatic shutoff, undertaking monthly measurements would be costly to facilities and would not provide greater assurance of water quality.

Similarly, the Proposed Rule would require that a chemical analysis of water be done at least annually, and in certain other specified circumstances (*e.g.*, when a new system is installed, when membranes are replaced). Again, this would be a needless exercise for systems such as ours. The Proposed Rule would also contain a standard regarding chlorine/chloramines levels.[7] Preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are pre-validated to ensure, through design or testing mandated by the FDA cleared system labeling, that the water produced does not contain chlorine or chloramines above set limits. Proposed 42 C.F.R. § 494.40(a)(1)(iii) imposes further extensive and burdensome requirements for water treatment equipment that are inapplicable to, and unnecessary for, preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water. In finalizing the Conditions for Coverage, CMS can eliminate these unnecessary burdens by adopting the changes identified in Section II below.

D. Requiring the Same AAMI Monitoring Standards for Preconfigured, 510(k) Cleared Systems Designed, Tested and Validated to Produce AAMI Water Imposes Special Burdens on Home Patients and Their Caregivers, Which is Inconsistent with the Intent of the Social Security Act.

Finally, because preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are predominantly used in patient homes, requiring unnecessary monitoring of these systems presents a burden to home therapy, which is inconsistent with Congressional intent. In enacting the Social Security Act ("SSA"), Congress expressed clear intent that "the maximum practical number of patients who are medically, socially and psychologically suitable candidates for home dialysis or transplantation should be so treated."[8] CMS' Proposed Rule is contrary to this expressed intent in that it unduly burdens home patients and their caregivers without any related benefit. The burden is further exacerbated by the location of the devices required to be tested. With these monitoring and testing requirements, dialysis facilities would be required to send nurses or technicians to patient homes with some frequency for no added health or safety benefit.

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6 70 Fed. Reg. at 6247 (proposed 42 C.F.R. § 494.40(a)(2)(i)).

7 70 Fed. Reg. at 6247 (proposed 42 C.F.R. § 494.40(a)(2)(c)).

8 SSA § 1881(c)(6).

This would act as a disincentive to the broader adoption of home therapy, reduce patient freedom (one of the significant benefits of home therapy) and impose greater costs without a related benefit.

II. REQUESTED CHANGE TO THE PROPOSED RULE

In order to provide dialysis facilities with the flexibility they need so that those using a preconfigured, 510(k) cleared system designed, tested and validated to produce AAMI quality water do not have to undertake burdensome and unnecessary water quality monitoring activities, we urge CMS to make two specific changes to the Proposed Rule:

1. Replace the first sentence of proposed 42 C.F.R. § 494.100(c)(1)(v) with the following (with the underlined text reflecting new suggested language):

"(v) Monitoring of the quality of water used by home hemodialysis patients in accordance with <u>either</u> the requirements specified in § 494.40(a)(1)(i) and (ii) of this part and conducting an onsite evaluation of the water system, <u>or, for preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water, the systems' FDA cleared labeling</u>."

2. Add a new 42 C.F.R. § 494.40(a)(3) to read as follows:

"(3) If a facility is using a preconfigured, 510(k) cleared system designed, tested and validated to produce AAMI quality water, as an alternative to following the water quality monitoring provisions set forth in paragraphs (a)(1) and (a)(2), the facility can satisfy this standard by following the systems' FDA cleared labeling to monitor water quality."

CONCLUSION

For the reasons stated above, NxStage believes that it is imperative that CMS allow dialysis facilities additional options within the Conditions for Coverage for ensuring the quality of water used in dialysis, whether at a facility or in a patient's home. Where preconfigured, 510(k) cleared systems designed, tested and validated to produce AAMI quality water are used, facilities and patients should be allowed to follow FDA cleared labeling to assure water quality as an alternative to the AAMI monitoring requirements incorporated in proposed 42 C.F.R. §§ 494.40 and 494.100. Failing to make this change would not be within the spirit of the stated intent of the Proposed Rule – to reflect advances in dialysis technology and focus on patient outcomes of care and eliminating unnecessary procedural requirements.[9]

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[9] 70 Fed. Reg. at 6185.

Once again, NxStage appreciates the opportunity to comment on the important issues in the Proposed Rule, and we hope that you will give consideration to our suggestions. Please feel free to contact me at 978-687-4736 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Michael Webb/LL

Michael J. Webb
VP, Quality Assurance/Regulatory Affairs

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RPA

Renal Physicians Association

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April 28, 2005

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Attn: CMS-3818-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities (CMS-3818-P); Proposed Rule

Dear Dr. McClellan:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. We are writing to provide input on selected portions of the proposed rule revising the Conditions for Coverage (CFC) for End Stage Renal Disease (ESRD) facilities. A bulleted summary of RPA's recommendations by subject area is included at the conclusion of this document.

Executive Summary

In order to ensure that the quality of patient care is advanced and does not deteriorate, RPA strongly believes it would be unwise to establish numerical standards in federal regulation, and that CMS should not do so in the absence of a specific, detailed process for revising and updating these standards as clinical guidelines evolve. In addition, RPA believes it would be appropriate for the CFC to address the issue of whether patients have some obligation to participate in efforts to optimize their care, as it is our opinion that cooperative, participatory patient involvement is a key component of an effective renal care delivery model. RPA also believes that the issue of facility discharge of patients must be considered together with the issue of physician discharge of patients, as failure to do so may result in a disruption of the patient's care. Lastly, RPA supports the empowerment of the dialysis facility medical director position as outlined in the proposed rule.

1700 Rockville Pike • Suite 220 • Rockville, MD 20852
Phone: 301/468-3515 • Fax: 301/468-3511 • email: rpa@renalmd.org • www.renalmd.org

Introduction

In general, RPA commends CMS for developing a thoughtful and reasonable proposal that is largely responsive to the multitude of issues raised by the renal community in recent years regarding an update of the CFC. These include: (1) establishment of a linkage in the CFC between existing regulations and clinical practice guidelines; (2) utilization of a process oriented toward continuous quality improvement (CQI); (3) elimination of duplicate data collection; and (4) evaluation of issues surrounding personnel requirements in ESRD facilities, among others.

RPA urges the Agency to take steps to ensure that more periodic review of rulemaking of this nature happens in order to avoid the almost three-decade interval that has occurred since the last iteration of these conditions was published in the mid-1970's. Similarly, while RPA does support and encourage the use of existing guidelines and external technical documents from groups outside of CMS such as the RPA, the Association for the Advancement of Medical Instrumentation (AAMI), the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (K-DOQI), we further urge CMS to develop a process to ensure that as these guidelines are updated, the CFC can reflect the revised guidelines. This issue will be discussed in greater detail below. Lastly, RPA would strongly recommend that CMS develop specific instructions to its carriers and surveyors regarding the intent of the CFC in order to minimize inappropriate variability in the interpretation of the CFC on the part of its contractors. RPA would welcome the opportunity to participate with CMS in the development of these instructions.

Subpart A

Definitions

RPA believes that there are several words or phrases that should be added to the list of proposed definitions included in Subpart A, in addition to some modifications to the existing definitions. These include:

- Nursing Home or Skilled Nursing Facility (SNF) Dialysis –These modalities appear to be included with 'Home Dialysis' in the proposed rule, and it is RPA's opinion that these services are sufficiently different from home dialysis to merit their own definition. The differences include: (1) the fact that more than one dialysis session can occur at the same time; (2) there is paid staff administering the treatment; (3) State and local regulations are in place governing the service; and (4) there is no family responsibility associated specifically with services rendered in these settings.

- Self-Dialysis –This modality can also be done in the facility and would not require complete "home training."

Further, given the establishment and use of 'standards' elsewhere in this regulation, as well as the tremendous significance of this concept as evaluation of dialysis care continues to evolve, RPA believes that the term 'standards' should be explicitly defined in the proposed rule for the purposes of the CFC. CMS should consider whether, for the purposes of this regulation, standards are to be used as minimum threshold values, minimum clinical standards, or current evidence-based, minimal, community-accepted standards. RPA would favor a definition based on current evidence-based, minimal, community-accepted standards for the specificity that such a definition would provide. Generally, RPA would urge that the word 'minimum' be included so that the work product of this effort serves as a "floor" for improvement (as opposed to being "ceiling"), in keeping with quality assessment (QA) principles and standard statistical processes.

Subpart B

Infection Control

In the proposed rule CMS invites comment on whether dialysis facilities should be required to adhere to the Healthcare Infection Control Practices Advisory's Committee (HICPAC) guidelines on "Hand Hygiene in Healthcare Settings" and "Guideline for Preventing Intravascular Device-Related Infections." While these are solid, evidence-based guidelines, we are compelled to note that there is controversy between HICPAC guidelines and those developed by the Society for Healthcare Epidemiology of America (SHEA) regarding the standard of care for preventing nosocomial transmission of multi-drug resistant Staph aureus and Enterococcus.

RPA strongly believes that whenever evidence-based guidelines are in conflict, they should either be reconciled or not used in the Conditions. Alternatively, many subsections use professional organization's current recommendations instead of numerical standards, allowing easier updating. RPA strongly endorses this approach.

Subpart C

Patient's Rights

While RPA concurs with the proposals that CMS has set forth regarding the facility's obligation to inform patients of their rights and responsibilities when they begin their treatment, we do believe it would be appropriate for the CFC to address the issue of whether patients have some obligation to participate in efforts to optimize their care. It is our opinion that cooperative, participatory patient involvement is a key component of an effective renal care delivery model, and as written the proposed rule sets patients on one side of the discussion and the renal care team on the other, and thus could potentially create an adversarial relationship between patients and the renal care team. We would suggest that the conditions should encourage patients to acknowledge the substance and content of the discussions on patient's rights and responsibilities and to ask questions, express concerns, and otherwise interact with the facility staff and renal care team at this juncture prospectively, rather than to seek resolutions to situations that may arise later in the course of the patient's treatment. Such a process would maintain a focus on patient centeredness, thereby providing the patient with the opportunity to share in the decision-making and responsibility for his or her own care, and can be the basis for an optimal relationship between the patient and the renal care team. [1]

Advance Directives

RPA believes that the current wording with regard to advance directives in this section could be strengthened. Currently the proposed rule requires *"the facility to inform patients of the right to establish an advance directive" and later notes that "after taking these factors into account, we believe it is prudent to consider adding advance directives as a requirement in the patients' rights condition of this proposed rule."*

At a minimum, dialysis units should be required to provide an advance care planning process in which patients are encouraged to 1) identify their preferred surrogate decision-maker in the event of incapacity, 2) complete an advance directive (called a medical power of attorney or durable power of attorney for health care or health care proxy) in which they name their preferred decision-maker, and 3) state how

[1] Crossing The Quality Chasm: A New Health System for the 21st Century Institute of Medicine National Academy Press, Washington DC, 2001

much leeway they want to give this decision-maker. This process preserves patient autonomy and helps nephrologists and dialysis units know with whom to make decisions if the patient loses capacity, a not infrequent occurrence for dialysis patients. In this advance care planning process, the dialysis unit should also identify if there are health states in which the patient would not want to be kept alive with dialysis or other forms of life support. The research shows that three-quarters or more of dialysis patients would not want to be kept alive if they had severe dementia or were in permanent coma. [2]

Further, it is our opinion that an informed patient's wish not to be resuscitated should be honored in the dialysis unit. Current research indicates that between 15-30% of dialysis units perform CPR on all patients regardless of whether they want it or not. The Renal Physicians Association and American Society of Nephrology *Position on Quality Care at the End of Life* reads: "To respect the wishes of patients who prefer not to undergo cardiopulmonary resuscitation, nephrologists shall issue do-not-resuscitate orders for their patients who request them. These orders shall be issued in the dialysis unit in a manner that respects patient confidentiality and yet ensures that those treating the patient are aware of them. Physicians are legally required to honor competent patients' treatment decisions. It is important to note, however, that a do-not-resuscitate order does not preclude other standard measures in dialysis treatment such as fluid resuscitation for intradialytic hypotension. A do-not-resuscitate order only becomes effective when the patient has experienced a cardiac or respiratory arrest." [3]

Patient Discharge from Facilities

Within the CFC there is an area of potential conflict with regard to facilities discharging disruptive or challenging patients in juxtaposition to physicians discharging these patients from their care. Presumably, the facility cannot dialyze a patient without an attending physician. However, the issue of what the facility's responsibility is in those instances where there is no physician available to serve as the attending physician is unclear.

Broadly, RPA strongly recommends that CMS consult and incorporate key elements of the positions developed by the Dialysis Patient-Provider Conflict (DPC) National Task Force, organized by the Forum of ESRD Networks, in its recent position statement (the Executive Summary of this document is appended to these comments). This statement addresses the rights and obligations of both patient and provider in the Medicare entitlement system. These points include, among others: (1) that providers have legal authority to refuse to treat patients who are acting violently or are physically abusive thereby jeopardizing the safety of others; (2) that the physician may terminate the physician- patient relationship only after taking steps necessary to fulfill ethical obligations and to avoid legal abandonment of patients; and (3) both the physician and the facility are obligated ethically, legally and by the current CFC to provide reasonable assistance to the patient in securing life saving treatment with another facility and/or nephrologist.

Timeframe for Completing Patient Assessment

In the NPRM CMS proposes criteria for the frequency of assessment and the reassessment of new patients, noting that *"a timely and comprehensive assessment is critical for planning patient care and achieving patient outcomes."* RPA fully supports the implementation of such criteria, and also concurs

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[2] Singer PA, Thiel EC, Naylor CD, Richardson RM, Llewellyn-Thomas H, Goldstein M, Saiphoo C, Uldall PR, Kim D, Mendelssohn DC. Life-sustaining treatment preferences of hemodialysis patients: Implications for advance directives. J Am Soc Nephrol 1995 Nov;6(5):1410-7.

[3] Renal Physicians Association/American Society of Nephrology Position on Quality Care at the End of Life, revised, 2002.

with CMS' belief expressed in the proposed rule that the requirement, though process-oriented, is necessary to prevent harm to the patient.

However, RPA would urge that the time interval for allowing facilities to complete the assessments be extended from 20 calendar days to 30 calendar days. We believe that a 20-calendar day timeframe would cause difficulties similar to the hardships created for rural and geographically challenged nephrology practices by implementation of the dialysis G-code system for physician reimbursement. The combination of the complexity of physician scheduling and the limited availability of the dialysis patient at times has resulted in the nephrologist being unable to provide the complete assessment of the patient in the month's time, much less the optimal four or more face-to-face interactions with the patient in a month's time. It is RPA's opinion that a requirement for providing the comprehensive assessment to the patient within 30 calendar days rather than the 20 days proposed in the rule will account for scheduling difficulties beyond the facility's and the dialysis care team's control.

Plan of Care

RPA supports CMS' proposals with regard to the comprehensive, 3-month reassessment of the patient plan of care and the elimination of the requirement for the patient long-term program. These proposals in general appear to increase the level of required care team activity for new patients and reduce the level of required care team activity for established patients. Such a change would serve to address the unique needs of patients who are new to dialysis while balancing this new administrative requirement by reducing the regulatory burden involved in providing care to relatively stable dialysis patients. RPA believes that this change is a common-sense approach that is responsive to the needs of dialysis facilities and renal care teams providing care across a population of kidney patients.

Transplant Status

RPA appreciates CMS' decision to remove the existing requirements for a separate long-term program from the conditions, and we support the proposal to retain the concept of transplant planning. We are compelled to note that at times issues in providing effective transplant planning to dialysis patients stem from the inability to receive necessary information from the transplant center in a timely manner. RPA would therefore urge CMS to account for the fact that in some situations where the dialysis facility is unable to properly provide transplantation referral evaluation, it may be due to a lack of information received from the transplant center. Further, we would offer that the use of written agreements between dialysis facilities and transplant centers, discussing for example the use of inclusion and exclusion criteria, would serve to confirm the responsibilities of both parties and reduce any miscommunications between facilities and transplant centers. RPA would lastly note our strong belief that the responsibility for transplantation referral must remain with the nephrologist.

Rehabilitation Status

While RPA supports CMS' increased focus on rehabilitation status within the CFC proposed rule, we do believe that there is a lack of clarity in the proposed condition that will make the criteria within it difficult for facilities to achieve. In the proposed rule CMS notes that *"this proposed condition does not hold facilities accountable for rehabilitative outcomes that are beyond their control; instead, this proposed standard requires that interdisciplinary team staff use a combination of medical treatment, education, counseling, and dietary regimens to maximize dialysis patient rehabilitative activities."*

From RPA's perspective, this condition is problematic in two ways. First, it is our belief that all rehabilitative outcomes are beyond the facility's control, so to infer that there are rehabilitative outcomes within the facilities' control does not reflect a comprehensive understanding of the state-of-the-art in this

area. [Processes are within a provider's control; outcomes are not.] Second, while CMS appropriately chooses not to "incorporate the use of any particular measure of rehabilitation" due to the lack of community consensus, we believe that establishing a requirement to "maximize" activities in federal regulation is by itself likely an invitation for misinterpretation of this condition by state surveyors or other personnel responsible for oversight. Such a definitional gap increases the probability that unintended adverse consequences will result from the literal application of this condition. For these reasons RPA would therefore urge CMS to proceed with caution in this area, and specifically to revise its language in this condition to remove the use of the word "outcomes" and to change the *requirement* to maximize rehabilitative activities to a *recommendation* to pursue such a course.

Finally, RPA recommends that CMS consider a philosophical shift in this area from an emphasis on 'rehabilitation' status per se to one that is more focused on functionality. It is our opinion that focusing on rehabilitation inherently implies return-to-work as an objective of this effort, which given the demographics of the Medicare ESRD beneficiary population (i.e., over age 65, usually with multiple co-morbid conditions present), is in the majority of situations unrealistic. RPA believes a focus on functionality that stresses participation in daily activities but not necessarily pertaining to a return-to-work would be more inclusive and generally appropriate for this patient group.

Implementation of the Patient Plan of Care

Within the CFC NPRM, CMS proposes a requirement that *"the facility must ensure that every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated by the physician's office and placed in the beneficiary's medical record."* RPA concurs with the necessity of all patients having complete monthly assessments, and we believe the proposal to require facilities to ensure that these visits occur is reasonable.

This provision of the proposed rule also expresses CMS' belief in the importance of physicians seeing their patients while they are on dialysis in order to monitor the quality of care delivered and to address clinical concerns and patient needs while in the treatment environment, and seeks comment whether this should be a requirement. RPA concurs with CMS' position with regard to the benefits of nephrologists seeing their patients while on dialysis for the reasons outlined in the proposed condition. However, we do not believe that the nephrologist should be required to see the patient while on dialysis for the mitigating considerations relating to geography, patient availability, and physician scheduling described previously.

We also would take issue with CMS' assertion in the regulation that such a requirement would not impose an additional burden in that if it becomes the facility's responsibility to comply with this requirement as a condition for coverage, the existence of the requirement alone becomes an additional burden. RPA does believe that in those situations where the nephrologist cannot see the patient while being dialyzed, the nephrologist should take responsibility for maintaining and making the medical record for those visits available to the facility as necessary.

RPA therefore concurs with CMS' assessment regarding the benefits of nephrologists seeing their patients while they are being dialyzed but believes that making this a requirement would be establishing a criterion that would be difficult for a substantial number of nephrologists and facilities to fulfill. We accordingly urge the Agency to make the language in this provision a recommendation rather than a requirement.

Care at Home

Within the section of the proposed rule addressing Care at Home, CMS includes the care provided in the nursing facility (NF) or skilled nursing facility (SNF) settings, noting that in these situations the NF or SNF is considered to be the patient's home. CMS goes on to seek comment on "*whether the current home dialysis regulations need to be modified to protect this vulnerable population.*" RPA believes that the needs of patients receiving their treatment in NFs or SNFs are clearly different than those of patients being dialyzed in their actual homes, and thus the Agency should develop criteria that reflect the distinct needs of the segment of the ESRD patient population receiving their care in the NF or SNF setting.

QAPI

As noted previously, RPA fully supports CMS' inclusion of a continuous quality improvement model for improving the care provided to Medicare's ESRD beneficiaries as part of the CFC. It is our belief that the program described in the proposed rule, the Quality Assessment and Performance Improvement (QAPI) program, while not perfect, does represent a positive step forward in this area, and the Agency should be commended for its efforts to incorporate these concepts into the federal regulation overseeing dialysis facility activities.

Among the related areas of concern that RPA has with the QAPI program are: (1) that the CFC inappropriately uses the K/DOQI guidelines as standards, directly contradicting the K/DOQI Disclaimer and Acceptable Use policy (appended to this document); (2) that the CFC inappropriately uses dynamic numerical standards in static federal regulation; and (3) that the CFC fails to specify procedures for reviewing, deleting, or updating these standards based on new information.

As noted previously, RPA supports CMS' prudent decision to use the work of external guidelines and technical documents in order to utilize the expertise of the leaders in the field of kidney care, to be efficient, and to avoid unnecessary duplication of effort. However, we urge the Agency to be prospectively cognizant of the downstream implications of such a decision. In the case of the K/DOQI guidelines, the disclaimer and acceptable use policy do indicate that the guidelines are not intended to define a standard of care. They are not intended to mandate what medical decisions should be made, or to replace the use of patient preferences or clinical experience in arriving at those decisions. The K/DOQI guidelines are intended to inform and enhance decision-making.

Facility Specific Standards for Enforcement

In the proposed rule, CMS provides proposed standards for the minimum delivered dose of dialysis (Kt/V) and anemia management that are aligned with clinical practice guidelines by the NKF-K/DOQI, and it is RPA's opinion that these proposals are reasonable. However, we do not currently support the inclusion of serum albumin as an indicator, in that it is inappropriate for use as an indicator due to its lack of actionability in a majority of ESRD patients.

CMS goes on to state that it is *"also soliciting comments on methods for using current NKF-K/DOQI clinical practice guidelines as facility-wide measures. For example, comments on the use of the statistically based threshold measures of performance would be especially helpful. Under such an approach, facilities in which a predetermined portion of patients fail to meet the selected clinical standards over some period of time, using a standard deviation, percentile-based, or some other method, need to develop a corrective action plan (CAP)."*

RPA's comments on this solicitation are noted as follows:

- Use of a model like the one above is a measurement of facility accountability, not quality improvement, because use of a CAP is not voluntary. Further, the Networks already mandate such a process.

- It is also our strong belief that potential use of proposed standards such as these is acceptable in aggregate on a facility-wide basis but should not be applied to individual physicians.

- RPA recommends use of appropriate statistical methodology for identifying low-performing facilities relative to normative data. For indicators that demonstrate a normal distribution, a threshold of two standard deviations below the mean would be consistent with a minimalist/thresholds-based model. For indicators with a skewed distribution, the comparable threshold is the one or preferably two standard deviations because this approach is consistent with a minimalist/thresholds-based model. For indicators with a skewed distribution, the comparable threshold is the 2.5th percentile; without such adjustment, use of percentiles (such as the bottom 10%, 25%, etc.) is arbitrary and without a basis in scientific evidence. [4]

- Because current literature indicates that some major patient outcomes such as mortality rate do not predict individual facility results from year to year, and that there may be reasonable explanations for a poor outcome, a "focused review" should occur before a CAP.

- RPA also urges CMS to consider issues raised in the recent report "Physician Clinical Performance Assessment: The State of the Art, Issues, Possibilities, and Challenges for the Future" which offers the following observations:

    - Use of a hierarchical, generalized linear statistical model to exclude other, non-facility actionable factors from affecting the standard or outcome – this would make the facility, medical director, or facility governing body accountable only for what they can control;
    - Case mix adjustment should be required in order to compare facilities;
    - Sample size should be comparable between/among dialysis facilities, based on the prevalence rate (how often it occurs per time interval) of the outcome in question
    - The desired outcome (e.g. mortality rate) must have an evidence-based link to the measure in question.[5]

CMS also notes in the proposed rule *"If we were to codify a clinical standards condition, the text would read as follows:"* RPA strongly urges CMS not to codify specific standards in the CFC. Standards should be reviewed, replaced or updated at some regular frequency. RPA recommends that if a facility doesn't meet evidence-based, community acceptable thresholds, this event should trigger a "focused review" by the Network Medical Review Board who should exclude allowable exceptions (such as a small number of patients, establishment of a new facility, etc.). If there are no significant allowable exceptions, a CAP should be considered at that juncture. The allowable exceptions should be predetermined, but alterable.[6]

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[4] Dr. Jennifer Daley, Christine Vogeli, MPH, Dr. David Blumenthal, MPP Institute for Health Policy Massachusetts General Hospital Physician Clinical Performance Assessment: The State of the Art. Issues, Possibilities, And Challenges for the Future The Institute for Health Policy Massachusetts General Hospital Partners HealthCare System

[5] *IBID*

[6] RPA White Paper on Accountability and The Use of Patient Outcomes In Developing Performance Measures, March 2004.

RPA Proposal for Development of a RUC-like Process for ESRD Standards Review

In accordance with the issues outlined above, RPA strongly believes that the establishment of numerical standards in federal regulation without an accompanying proposal for creating a structure to periodically review these standards not only fails to account for the continually evolving nature of scientific and medical knowledge, but also fails to do what is best for the nation's ESRD patient population. While RPA does not argue with the benchmark values that are assigned to indicators such as Kt/V or anemia management in the proposed rule, we do believe that it is imperative for CMS to develop a process for periodic and regular review of these values. Our interpretation is that use of such a process is consistent with positions on this issue by federal government entities such as guideline development recommendations from the Agency for Healthcare Research and Quality (AHRQ), the Office of Management and Budget's (OMB) Circular A-119, and National Technology and Transfer Act of 1995.

For these reasons, RPA urges CMS to consider the use of a defined methodology for the review of the standards outlined in the CFC, as well as for advances in technology and knowledge (such as, for example, machines that can perform short daily dialysis). This process should periodically review the standards or advances, validating them if appropriate, updating them or replacing them if necessary, at prescribed intervals. An analogous process that has successfully withstood the test of time can be found in the American Medical Associations' Relative Value Update Committee (RUC), which develops the relative values assigned to all physician CPT services in the Medicare fee schedule resource-based relative value scale (RBRVS).

RPA recognizes that CMS as a federal agency may have its ability to establish such a methodology limited by the requirements of the Federal Advisory Committee Act (FACA). For this reason, RPA would welcome the opportunity to be the convening organization for the ongoing development, review, and update of these standards for the ESRD Facility Conditions for Coverage, and otherwise by the renal care community as appropriate; this letter can be considered RPA's official notice of intent to CMS to volunteer to serve in this role.

Subpart D

Responsibilities of the Medical Director

As with other portions of the CFC proposed rule, RPA generally believes that the responsibilities of the dialysis facility medical director as outlined in Subpart D are for the most part reasonable and comprised of activities that should already be carried out by medical directors who are appropriately fulfilling their roles. It is our opinion that it is appropriate for dialysis facility medical directors to accept responsibility for the accountability assigned in this section of the regulation.

Under this condition, CMS discusses the existing requirements to be the director of a renal dialysis facility, and the necessity of "*assuring the adequate training of nurses and dialysis technicians in dialysis techniques*". In the same spirit, RPA would strongly recommend that the Governing Bodies of dialysis facilities should be responsible for the initial, sufficient training of the medical director. We believe that full and open discussion and disclosure of the expectations for these individuals at the outset of the relationship between the facility governing body and the medical director will serve to reduce any subsequent problems that may arise resulting from differing interpretations of the medical director's responsibilities and expected level of oversight of facility activities.

This section of the proposed rule also solicits comments on "*adding language to this regulation under the Medical Director condition to more specifically state Medical Director responsibilities in regard to ESRD facility attending physicians.*" RPA would urge CMS to require governing bodies to outline an

understandable and in-force process defining the authority of the medical director in addressing attending physicians or other staff members who are not performing adequately. Use of a uniform process in this area that includes peer-review, directed education and other quality improvement techniques will increase the transparency of these activities and minimize issues arising from poor communication.

Governance

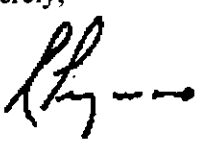
Within the Governance section of the CFC under Discharge and Transfer Policies and Procedures, CMS assigns responsibility for discharge and transfer policies to the Medical Director, and subsequently seeks comment on "*our proposal to hold the dialysis facility accountable for their staff adherence to the facility's patient discharge or transfer policies and procedures.*" RPA agrees that it is appropriate for this responsibility to be assigned to the Medical Director but also believes that it should be shared with the governing body in that some facilities involuntarily discharge patients without input from a nephrologist or medical director.

Furnishing Data and Administration for ESRD Program Administration

In the proposed rule CMS notes that "*an additional problem in using minimum standards for accountability purposes is the possibility of 'cherry picking' and decreased access to dialysis for some patients,*" and goes on to solicit comments on how the incentives to "cherry pick" could be minimized. Cherry picking can only be prevented by producing performance measures that accurately reflect the predominant control over the resultant measure or outcome by the person or facility held accountable for the performance. If other actors (the patient, other healthcare providers, institutions, or other entities) affecting the delivery of healthcare have a *significant* impact on the measure results, then the person or facility held accountable (thus without having significant control over the outcome/measure) will be encouraged to cherry pick. Cherry picking can also be avoided if appropriate exclusion criteria are developed for measure calculation. For example, if considering the rate of patients with AV fistulas, excluding patients with past history of four or more failed accesses or patients with documented needle phobia may be appropriate exclusion criteria.[7]

As always, we welcome the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's ESRD patients, and we stand ready as a resource to CMS in its future endeavors.

Sincerely,



Robert Provenzano, M.D.
President

[7] *IBID.*

Renal Physicians Association
Recommendations for Revisions to
CMS' Proposed Conditions for Coverage

General

- CMS should ensure that more periodic review of rulemaking of ESRD facility Conditions for Coverage occurs.
- CMS should ensure that as the underlying external guidelines of the CFC are updated, a process is in place to ensure the CFC can reflect the revised guidelines.
- CMS should develop specific instructions to its carriers and surveyors regarding the intent of the CFC in order to minimize inappropriate variability in the interpretation of the CFC on the part of its contractors.

Definitions

- RPA believes that a separate definition for 'nursing facility' and 'skilled nursing facility' dialysis should exist apart from the definition for 'home dialysis'.
- CMS should define the term 'standards', which should be based on current evidence-based, minimal, community-accepted standards.

Infection Control

- Whenever evidence-based guidelines are in conflict, such as may be the case in the area of infection control, they should either be reconciled or not used in the Conditions.

Patient's Rights

- The CFC should address the issue of whether patients have some obligation to participate in efforts to optimize their care, as it is RPA's opinion that cooperative, participatory patient involvement is a key component of an effective renal care delivery model.

Advance Directives

- CMS must strengthen and update the passages of the proposed rule related to advance directives in order to reflect current literature.

Patient Discharge from Facilities

- CMS must consider the issue of facility discharge of patients together with the issue of physician discharge of patients, as failure to do so may result in a disruption of the patient's care.
- CMS must consult and incorporate key elements of the positions developed by the Dialysis Patient-Provider Conflict (DPC) National Task Force.

Timeframe for Completing Patient Assessment

- The time interval for allowing facilities to complete patient assessments should be extended from 20 calendar days to 30 calendar days.

Plan of Care

- RPA supports CMS' proposals with regard to the comprehensive, 3-month reassessment of the patient plan of care and the elimination of the requirement for the patient long-term program.

Transplant Status

- CMS should account for the fact that in some situations where the dialysis facility is unable to properly provide transplantation referral evaluation, it may be due to a lack of information received from the transplant center.
- CMS should promote the use of written agreements between dialysis facilities and transplant centers to confirm the responsibilities of both parties and reduce any miscommunications between facilities and transplant centers.
- CMS should reiterate that the responsibility for transplantation referral must remain with the nephrologist.

Rehabilitation Status

- CMS should proceed with caution in the area of rehabilitation status, and specifically revise its language in this condition to remove the use of the word "outcomes" and to change the *requirement* to maximize rehabilitative activities to a *recommendation* to pursue such a course.
- CMS should consider a philosophical shift from an emphasis on 'rehabilitation' status per se to one that is more focused on functionality.

Implementation of the Patient Plan of Care

- CMS should not establish a requirement that the nephrologist see the patient while on dialysis for mitigating considerations relating to geography, patient availability, and physician scheduling.
- In those situations where the nephrologist cannot see the patient while being dialyzed, the nephrologist should take responsibility for maintaining and making the medical record for those visits available to the facility as necessary.

Care at Home

- CMS should develop criteria that reflect the distinct needs of the segment of the ESRD patient population receiving their care in the NF or SNF setting to differentiate these needs from patients being dialyzed in their actual homes.

Facility Specific Standards for Enforcement

- RPA recommends use of appropriate statistical methodology for identifying low-performing facilities relative to normative data.
- RPA recommends that in the situation where a facility experiences poor outcomes, a "focused review" should occur before a corrective action plan (CAP).
- **RPA strongly recommends that CMS not codify specific standards in the CFC.**
- CMS should establish a 'RUC'-like process for the ongoing development, review, and update of these standards for the ESRD Facility Conditions for Coverage, and RPA volunteers to serve as the convening organization for such a body.

Responsibilities of the Medical Director

- RPA strongly recommends that the Governing Bodies of dialysis facilities be responsible for the initial, sufficient training of the medical director.
- CMS should require governing bodies to outline an understandable and in-force process defining the authority of the medical director in addressing attending physicians or other staff members who are not performing adequately.

Governance

- RPA agrees that it is appropriate that responsibility for staff adherence to the facility's patient discharge or transfer policies and procedures to be assigned to the Medical Director, but also recommends that it be shared with the dialysis facility governing body.

APPENDIX I

Decreasing Dialysis Patient-Provider Conflict
National Task Force
Position Statement on Involuntary Discharge

Executive Summary

The Task Force believes that there is a substantial need to give providers guidance regarding the Ethical, Legal and Regulatory issues related to the involuntary discharge of ESRD patients by either the nephrologist or a certified dialysis center or facility. Most ESRD patients are covered by the Medicare ESRD Program and as such are entitled to receive a payment subsidy to their ESRD providers by the federal government for the life saving chronic treatments they require. Dialysis facilities become certified for this purpose and accept Medicare funding to provide these treatments and other services to Medicare Beneficiaries. When conflicts arise related to patient behaviors that are deemed unacceptable by the providers, then questions arise as to the rights and obligations of both the patient and provider in the Medicare entitlement system. This paper sets forth the following positions:

- Medicare beneficiaries with ESRD are entitled to partial government payment to providers for chronic dialysis treatments under the Social Security Act.
- Providers have legal authority to refuse to treat patients who are acting violently or are physically abusive thereby jeopardizing the safety of others.
- The use of contracts to facilitate effective and efficient use of facilities is permissible.
- Although a patient may unilaterally terminate the patient-physician relationship, the physician may terminate the physician- patient relationship only after taking steps necessary to fulfill ethical obligations and to avoid legal abandonment of patients.
- A certified facility cannot provide dialysis without a treating physician and thus must discharge a patient if the treating nephrologist terminates the patient physician relationship, or transfer the patient's care to another treating nephrologist within that facility. However, both the physician and the facility are obligated ethically, legally and by regulation to assist the patient in securing life saving treatment with another facility and/or nephrologist.
- It is unethical for patients to be left without treatment based solely upon non-adherent behaviors that pose a risk only to themselves i.e., nonadherence to medical advice.

Groups of providers should not exclude patients from acceptance and treatment from all their facilities or other physicians, except for irreconcilable cases of verified verbal/written/physical abuse, threats or physical harm. These groups should endorse and act on the ethical obligation to transfer patients to others within their group. An important purpose of transfer is to ensure that personality, language or cultural issues particular to an individual patient, professional or facility are not significant causes of the problem behavior of the patient.

APPENDIX II

K/DOQI™ Disclaimer and Acceptable Use Policy

Section I: Use of the Guidelines

These guidelines are based upon the best information available at the time of publication. ***They are designed to provide information and assist decision-making. They are not intended to define a standard of care, and should not be construed as one.*** Neither should they be interpreted as prescribing an exclusive course of management. Individual judgment by responsible clinicians is paramount in treatment of chronic kidney disease.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every health-care professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

The recommendations for research contained within this document are general and not meant to imply a specific protocol.

Renal

Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085-6730
847.473.6030

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Baxter

May 5, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P: Conditions for Coverage for End Stage Renal Disease Facilities

Dear Administrator McClellan:

Baxter Healthcare is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with our comments to the Proposed Rule for the Conditions for Coverage for End Stage Renal Disease Facilities (70 Fed. Reg. 6184 2005). We support CMS's efforts to update to the current Conditions, which have not been substantively updated since that time. Further, we applaud the agency's clear attempt to move toward more patient-centric, outcomes-based review, as opposed to the current process-oriented system. It is particularly refreshing to see the agency's focus on the patients' rights to be educated on all modalities of therapy and to be involved in their care in a meaningful, ongoing manner.

CMS and Congress have indicated support for the promotion of home-based therapies. We further applaud the recent efforts of CMS to support this goal and to assure that patients are provided information and equal opportunity access to all dialysis modalities. Not only does this represent the best clinical practice for many existing and future patients, it also addresses the fundamental financial and non-financial resource limitations that CMS and the renal industry are and will be facing. Home therapy keeps patients involved in their care, providing for a more efficient use of scarce RN's available to cover the growing ESRD population. It further provides the facilities with a more flexible means of caring for the patients in a manner consistent with the schedule and lifestyle needs of the patients and their family members. An additional benefit is that home therapy conserves the Medicare budget. According to the 2004 USRDS report (Table K.20), Medicare pays over 30 percent more per patient-year of therapy for hemodialysis than for the principal home dialysis modality used in the U.S., peritoneal dialysis. Mandating consistency in the way facilities assess all patients for home therapy suitability and assuring they provide the opportunity for it in all appropriate patients is essential. This is consistent with the statutory mandate of Section 2145 of Publication L. 97-35 which amended Section 1881 of the Social Security Act (SSA), and requires CMS to develop mechanisms to facilitate greater use of home dialysis.

While the agency is to be congratulated for their thoughtful and careful crafting of the proposed Conditions, we believe there are several areas that can be strengthened to more effectively achieve CMS, patient and Congressional quality targets. Specifically, we plan to address issues relating to the following: general definitions; patient safety; physical environment; patient rights; patient education and access to desired therapy options; informed consent; patient assessment and care plans; dialysis personnel training; quality assessment and performance improvement; markers for outcomes measurement; and patient satisfaction.

Definitions

Our concern in the definitions given is specific to the definition of "home" with regard to home dialysis and patients in nursing homes (NF's and SNF's). NF's and SNF's should be considered home settings regardless of whether the patient is a permanent or transient resident, if the patient has elected to be on home therapy. Currently, patients who are in NF's or SNF's on a temporary basis are not considered "home" patients. This is problematic and limits patient choice. If the patient has expressed a desire for home therapy, in the form of either peritoneal dialysis or home hemodialysis, and if their intended treatment upon disposition is a home-based therapy, then the interim residence should also be considered "home." (Additional comments relating to this are found on page 6.)

Patient Safety

Infection Control (494.30): We believe it was an oversight that the Medical Director was not expressly listed among the facility team members who must be notified in the event of an infection control issue. Obviously, the facility Medical Director is responsible for the medical care delivered to the population of the unit and he/she must be informed of and involved in the planning for resolution of all potential infection control matters.

Physical Environment

Patient Care Environment (494.60b): Patient privacy and confidentiality is an ongoing issue in the dialysis setting. In order to offer the highest level of privacy for ESRD patients, and in keeping with HIPAA, the agency should require all facilities to make available a place for confidential interviews with patients and families and for privacy if the patient's body is to be

examined or exposed in a manner that is deemed by the average patient to violate their privacy. (Reference: CMS HIPAA Fact Sheet; www.hhs.gov/news/facts/privacy.html)

We recommend that CMS encourage all facilities to make available home dialysis options either directly or indirectly. Further, any new facility, or one planning to expand stations, should include training space for home dialysis. Currently, fewer than half of US dialysis facilities directly provide the most common home dialysis treatment, peritoneal dialysis. This is not consistent with optimizing patient access to therapy options. Encouraging new units to provide for home training space may assist in attaining a more appropriate use of home-based therapies across the US.

Patients' Rights

Patients' Rights (494.70): It is the intent of CMS to assure that all patients have their rights explained to them. Unfortunately, there is no current mechanism in place to assure that the patients understand the information being provided to them. Thus, while a dialysis staff member may currently document that they have discussed facility policies and patient rights, there is no validation that the patient actually understood their rights or how to ask for help. (Johnstone S, *Advances in Chronic Kidney Disease*; 11(2):210-16, 2004.) CMS should require that facility staff not only explain a patient's rights, but also confirm that patients demonstrate evidence of understanding the materials presented. Such requirement should extend beyond general patient rights and should apply to all aspects where there is an expectation that the patient is a participant in their care or the care planning process.

Informed consent can only be given if a patient is provided the appropriate information with which to make their choices. Currently, patient education with regard to dialysis modality is not sufficient for many patients to make an informed decision for their care. Facilities should be required to objectively inform patients of all treatment options (home or facility based treatment, all dialysis modalities and transplantation) available to them prior to the initiation of treatment and subsequently with a frequency no less than annually. This is a requirement of the long-term care plan in the existing Conditions, which CMS proposes to eliminate. We do not believe it is CMS's intent to remove the responsibility of the units to inform patients of their modality options and to update that information over time. Therefore, we oppose elimination of this requirement.

Access to Care: Patient access to their choice of therapy is also critical. Patients need to know not only what types of therapies are available, but also where they may get additional information or receive their therapy of choice. CMS should require any facility that does not directly offer home dialysis to provide patients with a list of facilities in their area/region who do provide home therapy.

Productivity: Patients initiating dialysis should be informed that they might be able to continue to work or go to school even though they are on dialysis. Many new patients believe they must stop work or school to qualify for Social Security disability because of their dialysis, when in fact they may be able to continue to work and keep their insurance benefits. The opportunity to work or go to school is optimized when patients receive pre-dialysis education that explains what to expect from their therapy. This is particularly true for patients on home dialysis as they benefit from a more flexible treatment schedule. (Rasgon S, *Advances in Peritoneal Dialysis*; 12:132-5; 1996)

Patient Assessment

Patient Assessment (494.80a): We congratulate the agency on detailing the need for assessment of the patient, not just the data, as evidenced by the requirement to evaluate the patient's "...ability, interests, preferences and goals..." However, adding a requirement that the unit must document the patient's involvement in their daily care would strengthen this language. If a patient does not participate in their care, the unit should be required to document the reason in the medical record and to develop a plan to attain greater patient participation.

Suitability for Home Therapy: As stated above, any patient who is not referred for home therapy should have the reason for non-referral noted in their initial care plan. This reason should be reassessed on a regular basis to see if it still applies. This effort should be an ongoing part of the facility's formal quality assurance performance improvement (QAPI) program. Documenting reasons for non-referral to home therapy and efforts to overcome those barriers should improve the facility's home therapy offering and make it more accessible to more patients.

Frequency of Assessment for New Patients (494.80b): The proposed Conditions outline a strict timeline for the initial assessment. We believe this is too stringent and may not allow the time for a facility to properly assess a patient's unique condition and needs. Thus, we propose that CMS allow a facility to have 30 days from the initial treatment to complete the initial assessment. However, as the patient adapts to therapy, it is critical that the unit reassess the patient needs and goals. We suggest that CMS require a comprehensive follow-up assessment within 90 days after the initial assessment and/or before the permanent dialysis access is placed if the patient had a temporary vascular access upon therapy initiation, especially if said access was placed emergently. For such patients, the unit should be required to present and discuss all modality options again before a permanent access is placed. Such an approach could allow a patient a more appropriate opportunity to consider peritoneal dialysis as a permanent modality.

As discussed earlier, greater use of home dialysis can offer significant benefits to patients and savings to Medicare.

Assessment of the Treatment Prescription (494.80c): CMS should clarify the language in this section to appropriately reflect the most current clinical recommendations for dialysis outcomes. While we applaud the attempt to link the Conditions to clinical data and to identify markers for measuring quality, this can also be problematic. By choosing standards for quality that are static, such as the KDOQI (or CPM's from KDOQI), CMS may be limiting, as opposed to encouraging, quality over time. For example, the stated KT/V goal for home peritoneal dialysis has evolved twice in the past few years. The 1997 PD Adequacy Guideline was opinion based. It was changed in 2000 and is about to change again. We recommend that fixed targets not be specified within the Conditions and that the quality markers be allowed to evolve as clinical standards evolve. Rather, CMS should identify as a standard the most current guidelines recommended each year from a preponderance of evidence provided by organizations such as K/DOQI, the International Society for Hemodialysis and the International Society for Peritoneal Dialysis.

Additional clarification is needed in the language when referring to the numeric value of "...KT/V quarterly..." when the intent is to state that the KT/V for peritoneal dialysis is measured quarterly, though the value is expressed in a result per week.

Patient Plan of Care

Development of the Patient Plan of Care (494.90a): The patient should be specified as a member of the team developing the initial plan of care. To be an effective member of the care team, patients must be informed of all elements of their care and receive complete and objective education of all available dialysis modalities. Where possible, and with the consent of the patient, their family or caregivers should also be educated on the elements of care so they may contribute to the modality decision process.

We strongly disagree with the agency's proposal to remove 405.21237(a)(c) that requires a home dialysis physician to participate in the care plan process even if the facility does not offer home dialysis. Unfortunately, it appears that this standard has neither been met by providers nor enforced by facility Surveyors. This standard is of paramount importance in assuring that patients are provided access to a home dialysis option during the care planning process. This is especially critical given that over half of the dialysis facilities in the US do not offer the most common form of home dialysis, peritoneal dialysis. CMS should incorporate this requirement into the new proposed care plan requirements to best guarantee that patients have ongoing access to

a home dialysis physician so that they can ask questions about home therapy as their medical condition, their needs or goals change.

Home Dialysis Status (494.90b): Every patient should be assessed for their potential as a home dialysis candidate. If a patient is a candidate for home dialysis, the plan of care must note the approach for pursuing this goal, or must note the rationale for the patient not being referred to home dialysis. If the patient's barriers to home dialysis can be overcome, there should be a stated plan for doing so, and this should be monitored over time to allow the patient to reconsider home care. Home dialysis has been shown to offer patients greater flexibility and likelihood of continued employment, which could provide significant savings to Medicare. Across the facility population, data identifying the non-medical barriers to home dialysis and the methods of overcoming those barriers should be monitored and included in the facility QAPI program. CMS should then require each Network to track this data to help identify ways to offer greater access to home-based care throughout the Medicare program.

Patient and Family Education (494.90c): Patients and family members need to be educated to assure that the patient can make an informed consent for treatment, and to help avoid or detect potential problems that decrease patient quality of life and increase Medicare costs. We support CMS's efforts to encourage that every patient and their family/caregiver(s), where appropriate, have education about ESRD, treatment options, and all elements of the care needed/provided. This can provide the opportunity for greater success whether they choose to dialysis in the center or at home.

Care at Home

Care at Home (494.100): We support the consolidation of all Conditions that apply to a home dialysis program, but find some contradictions that need to be addressed.

Home Dialysis Monitoring (494.100b): Home dialysis is different from in-center care and it is appropriate to apply different standards of monitoring these patients. We strongly support the CMS requirement that the facility retrieve and review treatment data at least every 2 months. We strongly oppose the proposed requirement that physicians see each home patient monthly, a position that is contradictory to the 2005 Final Physician Fee Schedule. Rather, we recommend in (494.100b4) that the physician should be allowed to physically visit with the patient as medically indicated to meet the unique needs of the home patient. This would make the new Conditions consistent with the 2005 Final Physician Fee Schedule that recommends, but does not require a monthly visit in order for the attending nephrologist to bill for monthly capitated

services for ESRD patients dialyzing at home. (2005 CMS Physician Fee Schedule, Fed Register: Nov 3, 2004)

Support Services (494.100c): Facilities have been providing for the monitoring of the patient's home adaptation, and, where needed, have provided visits to the home to observe and make recommendations for change. This is not needed by all patients and may be deemed a privacy issue by some. As such, it should be left up to the team developing the care plan to determine if a home visit would be helpful.

Additionally, the sentence that states facilities "must purchase and deliver necessary supplies and equipment" should be modified to state "must purchase or rent and be responsible for organizing delivery of necessary supplies and equipment..." This is because many facilities rent or lease dialysis equipment, rather than purchase it. Also, many providers negotiate agreements with suppliers for direct home delivery of supplies or equipment rather than delivering these themselves.

Staff Requirement (494.100): CMS should change the reference to the home dialysis RN to state simply the home dialysis nurse. Many programs have highly trained and qualified LPN's who perform patient training. Facilities are required to have an RN manage the home program, but patient training can be effectively provided by either an RN or an LPN.

Dialysis in a NF or SNF: CMS seeks input on how to treat dialysis performed in the nursing home setting. As previously stated in the section on definitions, a patient should be considered a "home patient" in the NF or SNF if their modality of choice is a home therapy regardless of whether the NF/SNF is their temporary or permanent residence. In the proposed section addressing dialysis in the nursing home, CMS focuses exclusively on hemodialysis and ignores the fact that peritoneal dialysis is also provided in the nursing home setting. It is appropriate to distinguish peritoneal dialysis in the nursing home as "home dialysis" as it does not have the same staffing or monitoring needs as center-based or home hemodialysis. If that differentiation is made, then hemodialysis in the nursing home setting might be more appropriately given a full Condition of its own. CMS recognizes the hardship of transporting ESRD patients from NF's/SNF's thrice weekly to freestanding dialysis facilities. If a greater effort is made to assess whether the NF/SNF patients are candidates for home dialysis modalities, and if peritoneal dialysis is supported, this hardship and additional expense may be avoided.

Quality Assessment and Performance Improvement

QAPI Program Scope (494.110a): As stated previously, CMS should avoid linking QAPI expectations to static standards of delivery of care (KDOQI/CPM's). Rather, CMS should strive to identify more timely measures as appropriate markers for quality. As proposed in the New Conditions, every facility would have Patient Satisfaction as one of the key elements of their QAPI program. Additionally, every program should include home dialysis status as one of their core elements for improvement. Published data shows the link between home therapy and improved patient satisfaction (Rubin HR et al, *JAMA* Vol 291:Number 6: 697-703; Feb 11, 2004). Throughout the Conditions, CMS emphasizes the need for objective patient education concerning care choices including modality selection. Several studies have shown that patients who are provided objective education of modality options are significantly more likely to elect home peritoneal dialysis as compared to patients who are not systematically educated on their options (Golper T, *Nephrology, Dialysis and Transplantation* Vol 16:Supplement 7: 20-24, 2001). Thus, CMS should support a requirement for objective modality education with mechanisms to evaluate and improve the effectiveness of the delivered education.

Personnel Qualifications

Personnel Qualifications (494.140): CMS has appropriately outlined a host of new responsibilities for Registered Nurses in the facilities, and proposed great new expectations for personnel training (494.140e). While this may be burdensome for some clinics, it is a step toward assuring that the staff in the unit have a better understanding of not only the mechanics of the therapy they are providing, but also of the potential complications and ways to detect and avoid them. There is a high turnover rate in dialysis clinics. Setting minimum standards for technician training and monitoring of new technicians by an RN is one way to enhance safety for all patients. CMS's proposed approach is consistent with the recommendations of the Forum of Networks in their report entitled "Designing a Collaborative Action Plan with ESRD Stakeholders." (reference www.esrdnetworks.org/DPPCfinalreport.pdf)

Governance

Adequate Number of Qualified and Trained Staff (494.180b): Rather than specify a number of RN's required at any given time in the dialysis unit, it would be more appropriate to simply say that the facility is required to assure that an adequate number of qualified and trained staff are present whenever patients are receiving treatment so that the patient to staff ratio is appropriate to meet the needs based on the acuity of the patient population being treated at that time. For

home dialysis programs, CMS should indicate that there should be a staff member available via phone, pager or email to respond to patient medical inquiries, as needed.

Furnishing Data and Information for ESRD Administration (494.180h): There should be mandatory annual reporting of facility aggregate data regarding home dialysis and barriers to any treatment modality. Further, data for the CMS Dialysis Compare Site should include home dialysis outcomes data and standardized patient satisfaction data.

Conclusions

In summary, we feel that the updated Conditions of Coverage for ESRD facilities are commendable. The move toward a focus on patient needs and goals and away from task-oriented surveys is laudable and should foster improved care and communication between patients, facilities, ESRD Networks and CMS. This change in the ESRD Conditions of Coverage offers an opportunity for CMS to further codify their support for greater access to and use of home therapy. Through requirements for appropriate education of patients and family members, CMS can help assure that all Medicare beneficiaries with ESRD are given a chance to make informed decisions, which reflect their medical and personal needs. Development of carefully considered interpretive guidelines and the survey tool for the new Conditions, along with appropriate training of ESRD surveyors on the new Conditions are the critical next steps in this process.

We appreciate the chance to review and comment on the proposed changes to the Conditions of Coverage for ESRD Facilities. As the agency continues to modify the Conditions and develops tools to implement them, we would welcome the opportunity to meet with you and your staff to offer input and expert assistance.

Sincerely,

Maria Galainena Johnson
GM U.S. Region

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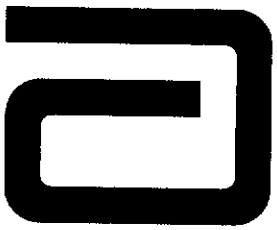
Tejal R. Vakharia
Director, Strategic Programs
Integrated Healthcare
Marketing & Policy

Abbott
200 Abbott Park Road
Abbott Park, IL 60064

Phone: (847) 938-5988
Fax: (847) 938-6606
E-Mail: tejal.vakharia@abbott.com



May 4, 2005

VIA HAND DELIVERY
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: **CMS-3818-P**: Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities. Comments on proposed §§ 494.20: Compliance with Laws and Regulations; 494.90: Patient Plan of Care; 494.110: Quality Assessment and Performance Improvement.

Dear Dr. McClellan:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's") Proposed Conditions for Coverage for End Stage Renal Disease Facilities [70 Fed. Reg. 6,184 (Feb. 4, 2005)] (the "Proposed Rule"). Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture, and marketing of pharmaceuticals and medical products. The company employs more than 55,000 people and markets its products in more than 130 countries.

We commend CMS's efforts to revise the requirements that End Stage Renal Disease (ESRD) dialysis facilities must meet to be certified under the Medicare program. Such revisions will undoubtedly positively impact patient care. However, we are writing to express concern with CMS's proposed Conditions of Coverage ("Conditions") included in §§ 494.20, Compliance with Laws and Regulations, 494.90, Patient Plan of Care and 494.110, Quality Assessment and Performance Improvement. Below, we set forth our comments on these sections of the Proposed Rule.

Summary of Recommendations

In the preamble to the Proposed Rule, CMS states that the revised Conditions for ESRD facilities would "focus on the patient and the results of the care provided to the patient, establish performance expectations for facilities, encourage patients to participate in their care plan and treatment, eliminate many procedural requirements from the current conditions for coverage, and preserve strong process measures when necessary to promote patient well being and continuous quality improvement."[1] We applaud CMS for proposing updates to these requirements with a focus on patient outcomes.

It is in the spirit of this shared interest of improving patient outcomes and incorporating performance benchmarks to encourage quality dialysis facility care that we submit the following comments to the Proposed Rule. In summary, these comments encompass the following recommendations:

§494.20: Compliance with Laws and Regulations This draft proposed Condition may imply that "off-label" use of drugs is no longer permissible. CMS should revise this Condition to clarify that it does not impose limits on the prescribing practices of nephrologists in the dialysis facility setting, which in effect, would constrain treatment innovations in a manner that could result in patient harm.

§494.90: Patient Plan of Care Advances in vitamin D science and the recognition of such advances throughout the dialysis community warrant inclusion of an evaluation of factors associated with renal bone disease within the patient plan of care. In addition, CMS should incorporate the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (K/DOQI) Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease as clinical performance measurements (CPMs) in this Condition to track the progress of dialysis facilities in this area.

§494.110: Quality Assessment and Performance Improvement (QAPI) In tandem with §494.90, CMS should revise the proposed QAPI guidelines for dialysis facilities to include a measurement of the presence of renal bone disease. CMS should incorporate the NKF K/DOQI Clinical Practice Guideline 8B.1 for Bone Metabolism and Disease in Chronic Kidney Disease as a CPM.

§494.20: Compliance with Laws and Regulations

CMS states that dialysis facilities "must use FDA-approved/cleared devices and adhere to the devices' labeling instructions" in conjunction with other statements regarding the use of "drugs and medical devices . . . [in] compliance with existing laws and regulations . . . [.]" This may imply that "off-label" use of drugs is no longer permitted.

> ***Recommendation:*** *The policy on the usage of off-label drugs as set forth in the Proposed Rule is inconsistent with what appears to be CMS's institutional position on this issue. We urge CMS to clarify that it does not impose limits on the prescribing practices of nephrologists in the dialysis facility setting, which in effect, would constrain treatment innovations in a manner that could result in patient harm. CMS should revise this provision by deleting references to drugs within the context of compliance with laws and regulations.*

It is self-evident that dialysis facilities must operate within legal and regulatory frameworks and we agree that they should do so to the fullest extent possible. We note, however, that the proposal appears to be inconsistent with CMS's institutional stance on coverage of unlabeled uses of medications. CMS's policy on the coverage of Medicare Part B cancer medications is a clear example of this policy position. Section 2049.4.C of the Medicare Carrier's Manual provides that Medicare contractors must not deny coverage for a cancer drug based solely on the absence of FDA approved labeling for the use, provided that specified compendia support the proposed uses.

Further evidence of CMS's institutional policy stance on the coverage of unlabeled uses of drugs can be found in the context of Medicare Part D. CMS posted draft guidance on the CMS web site with regard to the coverage of off-label uses of drugs in the context of the Part D Program.[2] In describing coverage of off-label drugs under Part D, CMS states that a prescription drug will qualify as a Part D drug[3] if the drug is used for a medically accepted indication as defined in §1927(k)(6) of the Social Security Act (the Act). The definition therein of "medically accepted indication" permits uses supported by a citation included, or approved for inclusion, in one of four compendia.[4] For

purposes of Part D, if a drug is prescribed for a medically accepted indication that appears in one of the compendia pursuant to §1927(k)(6) of the Act, CMS does not impose the additional requirement contained in the Proposed Rule that a drug must be used for those purposes listed on the label originally approved by the FDA.

§494.90: Patient Plan of Care

As CMS has previously recognized the scientific progress made in the area of bone disease and is in the process of implementing CPMs measuring bone disease factors, the agency should include in the evaluative categories for Patient Plan of Care a specific, parallel measure for the presence of renal bone disease.

> ***Recommendation:*** *Advances in vitamin D science and the recognition of such advances throughout the dialysis community warrant inclusion of an evaluation of factors associated with renal bone disease within the patient plan of care. The NKF K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease should be incorporated as CPMs in the Conditions for purposes of tracking dialysis facilities' progress in this area.*

We agree with CMS's belief as set forth in the Proposed Rule[5] that systematic patient assessment is essential to improving quality of care and patient outcomes. CMS states:

> "The information generated from the patient assessment is a vital tool for developing a patient's care plan and subsequent treatment. A comprehensive patient assessment allows the dialysis facility to monitor the patient's progress toward achieving the desired care outcomes and adjust the plan of care and treatment prescription as necessary."

CMS recognizes that existing regulations do not set forth specific criteria that dialysis facilities must include in a patient assessment. CMS further states: "over the past 25 years, research has improved our knowledge of the components important to assessing and treating the dialysis patient so that improvements in quality of life and morbidity and mortality rates have been achieved."[6] Significantly, researchers in the dialysis community have demonstrated the survival benefits of vitamin D, as published in the Journal of the American Society of Nephrology.[7] This cohort study proved the hypothesis

that therapy with injectable vitamin D improves the survival of patients who have ESRD and undergo chronic hemodialysis.

Indeed, CMS also recognizes the scientific progress made in the area of renal bone disease and has proposed to include evaluation of factors associated with renal bone disease in the patient assessment criteria. Working with ESRD Network 11, CMS aims to implement CPMs to assess and track bone disease management in dialysis facilities. We understand that these CPMs are to be based on the NKF K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Patients with Chronic Kidney Disease (Oct. 2003).[8]

Notwithstanding the agency's recognition of progress in this area, in setting forth the evaluative categories for *Patient Plans of Care* in proposed §494.90, CMS does not include a specific, parallel measure of the presence of renal bone disease. This appears to be inconsistent with CMS's statement that the patient assessment serves as a basis for the patient plan of care.[9] Furthermore, in setting forth "Rehabilitation Status" as one element of the patient plan of care, CMS itself acknowledges that:

> "[a]dvances in technology and pharmacology have offered the possibility of significant improvements in the well-being of dialysis patients. More efficient dialysis equipment, the development of the synthetic hormone erythropoietin and *active vitamin D*, for example, represent important breakthroughs in quality of life areas." (emphasis added).[10]

As CMS has acknowledged a scientific basis for including anemia management as an evaluative category in the patient plan of care, advances in vitamin D science and the recognition of such advances throughout the dialysis community warrant inclusion of an evaluation of factors associated with renal bone disease within the patient plan of care.[11] In the interest of setting forth measures by which to track dialysis facilities' performance in this area of patient care, we urge CMS to amend the Proposed Rule to include a specific CPM of bone disease, mirroring the NKF K/DOQI guidelines, which include Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease.[12]

§494.110: Quality Assessment and Performance Improvement

The same rationale that forms the basis for our comments with respect to proposed §494.90, Patient Plan of Care, also informs the comments we set forth with respect to §494.110 of the Proposed Rule, Quality Assessment and Performance Improvement.

> ***Recommendation:*** *CMS should revise the proposed QAPI guidelines for dialysis facilities to include a measurement of the presence of renal bone disease. The K/DOQI Clinical Practice Guideline 8B.1 for Bone Metabolism and Disease in Chronic Kidney Disease should be used as the basis for this measurement.*

As we previously noted, CMS recognizes the scientific progress made in the area of renal bone disease and has proposed to include evaluation of factors associated with renal bone disease in the patient assessment criteria. In our comments to proposed §494.90, we urge CMS to solidify this acknowledgment, which would ultimately positively affect patient care, by revising that section to include an evaluation of the factors associated with renal bone disease within the patient plan of care. In tandem with this revision, CMS should revise proposed §494.110 to include a specific, parallel measure of the presence of renal bone disease as part of the QAPI guidelines for facilities. The scope of proposed §494.110 is similar to that of the patient plan of care, encompassing related areas such as adequacy of dialysis, nutritional status, anemia management, and vascular access. To effectively advance the aim of improved patient outcomes with, as CMS itself stated, the development of active vitamin D and other agents, we believe the inclusion of the bone disease performance measure is also appropriate here.

As CMS works toward standardizing clinical performance and quality improvement measures, we also recommend that CMS implement the parameters for parathyroid hormone (PTH) levels contained in the K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. In particular, Guideline 8B.1 states:

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Joshua J. Ofman, MD., MSHS
Vice President, Reimbursement
& Payment Policy

AMGEN

Amgen
555 13th Street, NW,
Suite 600 West
Washington, DC 20004
202.585-9663
Fax 202.585-9730
Email jofman@amgen.com

CMS-3818-P-34

May 5, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities; Proposed Rule (CMS–3818–P)

Dear Administrator McClellan:

Amgen, the world's leading biotechnology company, appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding the Conditions of Coverage for End Stage Renal Disease Facilities, published in the Federal Register on February 4, 2005 (the Proposed Rule).[1] As a science-based, patient-driven company, we are vitally interested in improving access to innovative new drugs and biologicals for Medicare dialysis patients and ensuring that beneficiaries continue to have access to existing drugs and biologicals. In this letter, we provide our comments regarding the proposed changes to the current Conditions for Coverage for facilities providing outpatient maintenance dialysis and related services to Medicare beneficiaries with end stage renal disease (ESRD).

Amgen applauds the agency's efforts to move the focus of the Conditions for Coverage from a process-orientated approach to a more patient-centered outcome approach. This shift is appropriate in the current operating environment, which has evolved into one with much more real-time reporting of patient conditions and faster adjustments in patient care plans than was envisioned in the design of the original Conditions of Coverage for dialysis facilities. The shift to a patient-centered set of proposed Conditions appropriately allows facilities to focus on the quality of care they provide rather than on meeting specific process requirements that may have little or nothing to do with patient care. After reviewing the Proposed Rule, we believe that CMS recognizes that the Conditions for Coverage should combine reasonable flexibility for

[1] 70 Fed. Reg. **6184** (Feb. 4, 2005).

dialysis centers with achievable clinical targets to ensure that dialysis patients receive high-quality care.

To that end, Amgen urges CMS to adopt several specific recommendations that should enhance both the dialysis center focus on patient outcomes as well maintain flexibility for the dialysis centers. These recommendations would also support CMS' efforts to ensure proper patient protections and Medicare payment safeguards.

With respect to anemia management under the Quality Assessment and Performance Improvement (QAPI) Program,[2] CMS should mandate that the National Kidney Foundation Kidney Disease Outcomes Quality Initiative ("NKF-K/DOQI™") Guidelines be used to identify the appropriate reference values for the minimum clinical standards under this program.

CMS should finalize its proposed requirement that the patient assessment include treatment plans for anemia.

CMS should mandate that the NKF-K/DOQI™ Bone and Mineral Management Guidelines be used to identify the appropriate tests and reference values into the Patient Assessment, the Patient Plan of Care, and the QAPI Program. Amgen also understands that CMS intends to incorporate these Guidelines into Clinical Performance Measures ("CPMs") later in 2005 and recommends that CMS consider incorporating the CPMs into the Conditions of Coverage Final Rule.

While Amgen recommends that CMS mandate the use of NKF-K/DOQI™ Guidelines in the above two areas, CMS should not incorporate specific clinical values into the Final Rule. Rather, the agency should adopt a more flexible mechanism to update NKF-K/DOQI™ guideline clinical targets through the use of sub-regulatory guidance to select the specific clinical values used in the Patient Assessment, Patient Plan of Care, and the QAPI Program. This approach, which should be transparent and include a comment process, would allow for faster updating of clinically appropriate targets for both anemia management and bone management than having to undertake notice and comment rulemaking to reflect changes to the pertinent Guidelines.

Mandating the Use of NKF-K/DOQI™ Guidelines for Anemia Management Standards for Patient Assessments and QAPI – ["Patients' Rights" and "QAPI"]

Reflecting the overall change in focus for the ESRD facility conditions of participation to emphasize the patient and the results of care provided to the patient, CMS proposes a new requirement for a patient assessment that the agency believes is a prerequisite for the provision of quality care.[3] This comprehensive assessment would be performed by an interdisciplinary team (composed of the patient, a physician, a registered nurse, a

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[2] 70 Fed. Reg. at 6243

[3] 70 Fed. Reg. at 6250 (proposed 42 C.F.R. § 494.90).

social worker, and a registered dietician). Part of this assessment includes an evaluation of the factors associated with anemia, such as hematocrit, hemoglobin and iron stores. The assessment must also include potential treatment plans for anemia, including the administration of erythropoietin ("EPO").[4] While current regulations require a written Patient Care Plan for all patients, based on an assessment of the patient's needs, there is no mandated patient assessment. The introduction of such an assessment is an appropriate step to improve consistency in patient care planning across the Medicare dialysis patient population and CMS should finalize this proposal.

We strongly recommend the adoption of the NKF-K/DOQI™ Guideline 4 to determine the appropriate target hematocrit/hemoglobin values when developing a patient assessment tool in dialysis centers. As the leading independent American science and patient organization focused on chronic kidney disease and dialysis, the NKF is well-positioned to objectively develop and update the treatment standards for this fragile patient population. To that end, Amgen also recommends that Medicare require the dialysis centers to use these Guidelines (and associated clinical targets) in the development of the Patient Assessment, the Patient Care Plan anemia management targets as well as the QAPI assessment values be based on the NKF-K/DOQI™ Anemia Management Guidelines.

As mentioned above, Amgen suggests that CMS use sub-regulatory guidance (transmittals, manual issuances, et cetera) instead of notice and comment rulemaking to update specific clinical target values (like the current NKF-K/DOQI™ anemia targets used in the Proposed Rule). This would allow Medicare to stay current with the NKF guidelines and avoid the time and effort needed for notice and comment rulemaking.

Incorporate a framework for Bone Metabolism and Disease Management in the Proposed Rule – ["Patients' Rights"]

The Proposed Rule identifies the need for bone metabolism and disease evaluation in the Patient Assessment section of the rule.[5] Amgen agrees that an evaluation of this condition is an essential part of a comprehensive patient care plan developed by a dialysis center. We believe, however, that as with anemia management, Medicare should also require a framework for bone metabolism and disease management that is more comprehensive. That framework would also be based on developing parallel Patient Care Plan and QAPI Conditions of Coverage components that would also be structured around the NKF-K/DOQI™ Guidelines. The recent excellent work in the development of the draft Bone Metabolism Clinical Performance Measures is a logical foundation to build upon for the appropriate NKF-K/DOQI™ standards to incorporate in a Final Rule.

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4 70 Fed. Reg. at 6250 (proposed 42 C.F.R. § 494.90(a)(3).

5 70 Fed. Reg. at 6249 (proposed 42 C.F.R. § 494.80(a)(5)).

Amgen recommends that any bone metabolism and disease management standards adopted in a Final Rule also rely on sub-regulatory guidance documents from Medicare for specific clinical targets in this therapeutic area so that future adjustments in the NKF-K/DOQI™ Guidelines can be efficiently updated without having to undertake notice and comment rulemaking.

Conclusion

Amgen and CMS share the goals of improving the health of the ESRD patients, ensuring access to therapies and continuing to improve the quality of care they receive. For these reasons, careful consideration must be given to any policy changes that may disrupt care or provide potential access problems to these patients at high risk for adverse health outcomes. To that end, the adoption of the NKF-K/DOQI™ Guidelines as the general structure for anemia management and bone metabolism and disease management in the Conditions of Coverage Final Rule would provide a public framework that is capable of timely updates. We believe that a flexible updating mechanism that uses sub-regulatory guidance best serves the interest of the patients and dialysis centers by allowing for timely and efficient revision of the clinical targets identified in a Conditions of Coverage Final Rule.

Amgen appreciates the opportunity to comment on the important issues raised in the Proposed Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies and that the shortfalls in the quality of care for this population as outlined in the 2001 GAO report referenced in the Proposed Rule continue to be aggressively addressed. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Andy Swire or myself at (202) 585-9500 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Joshua Ofman, M.D. and MSHS
Vice President, Reimbursement and
Payment Policy Global Government Affairs

GUIDELINE 8B. VITAMIN D THERAPY IN PATIENTS ON DIALYSIS (CKD STAGE 5)

8B.1 Patients treated with hemodialysis or peritoneal dialysis with serum levels of intact PTH levels >300 pg/mL (33.0 pmol/L) should receive an active vitamin D sterol (such as calcitriol, alfacalcidol, paricalcitol, or doxercalciferol to reduce the serum levels of PTH to a target range of 150 to 300 pg/mL (16.5 to 33.0 pmol/L). (EVIDENCE).[13]

We would be pleased to discuss any of these issues with you in greater detail. Please feel free to contact me if you have any questions or if you need additional information.

Sincerely,

Tejal R. Vakharia
Director, Strategic Programs
Integrated Healthcare Marketing & Policy

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[1] 70 Fed. Reg. at 6,184.

[2] See "Medicare Part B versus Part D Coverage Issues," March 23, 2005, http://www.cms.hhs.gov/pdps/PARTB-Ddocument.pdf.

[3] Section 1860D-2(e) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) indicates that "Covered Part D Drug" is a drug that

may be dispensed only upon a prescription, is approved by the Food and Drug Administration (FDA) (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Social Security Act) used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act).

[4] As indicated in §1927(k)(6), the compendia include: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, DRUGDEX Information System, and American Medical Association Drug Evaluations.

[5] 70 Fed. Reg. at 6,203.

[6] Id.

[7] "Activated Injectible Vitamin D and Hemodialysis Survival: A Historical Cohort Study," Ming Teng, Myles Wolf, M. Norma Ofsthun, J. Michael Lazarus, Miguel A. Hernán, Carlos A. Camargo Jr., and Ravi Thadhani. J. Am. Soc. Nephrol. 16: March 21, 2005. doi: 10.1681/ASN.2004070573.

[8] National Kidney Foundation. Am J Kidney Disease 42:S1-S202, 2003 (suppl 3). See also NKF web site for specifics on this guideline: http://www.kidney.org/professionals/kdoqi/guidelines_bone/index.htm

[9] 70 Fed. Reg. at 6,204.

[10] Id. at 6,207.

[11] In the alternative, we recommend that CMS provide for a process whereby the agency can analyze at specified intervals functional areas for clinical performance measures and suggest revisions if necessary.

[12] See Note 8.

[13] Id.

KIDNEY CARE
PARTNERS

May 5, 2005

05 MAY -5 PM 4:35

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3818-P: Conditions for Coverage for End Stage Renal Disease Facilities

Dear Administrator McClellan:

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for the Conditions for Coverage for End Stage Renal Disease Facilities (Proposed Rule). 70 Fed. Reg. 6184 (2005). KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[1]

In brief, KCP applauds the agency's efforts to shift the focus of the Conditions for Coverage from a process-orientated approach to a patient outcome point of view. Even so, we have some concerns that some of the proposed Conditions extend into clinical and health service delivery areas over which ESRD facilities have no control.

[1] A list of Kidney Care Partners coalition members is included in Attachment A.

To summarize, KCP believes:

- The shift to a patient-centered set of proposed Conditions appropriately allows facilities to focus on the quality of care they provide rather than on meeting specific process requirements that may have little or nothing to do with patient care;

- Given the fact that the ESRD program is the only Prospective Payment System (PPS) in the Medicare program that does not have an annual update mechanism, the agency should take into account the direct-cost impact of implementing the proposed Conditions for Coverage on dialysis facilities to ensure that they do not create an additional set of unfunded mandates on the program;

- CMS should hold facilities responsible for only those activities and outcomes over which they do have control; and

- As CMS recognizes, the Conditions for Coverage should maximize flexibility to ensure that patients receive high-quality care; however, some of the proposed Conditions are overly prescriptive and contrary to this goal.

In this letter, KCP does not provide an exhaustive analysis of each provision within the Proposed Rule. Rather, our members seek to provide the agency with overarching concerns and to explain them through specific examples. These examples are not exhaustive and do not identify all of the concerns KCP members have about the Proposed Rule. Rather, the examples point to the type of issues that warrant further evaluation and review by CMS.

We encourage the agency to review the comments submitted by individual KCP members for more detailed analyses of the individual provisions. Thus, we hope that CMS can look to our general recommendations to establish a set of general principles that it will use to evaluate each proposed Condition as the agency works to finalize the Proposed Rule. Specifically, we suggest that CMS evaluate the Conditions to ensure that each one:

- Allows facilities to provide high-quality care to patients without imposing unnecessary burdens;

- Is cost-effective and avoids placing significantly higher costs on facilities, especially if the benefit to patients is questionable;

- Recognizes those activities and outcomes over which dialysis facilities are practically able to exercise control and does not hold them responsible for activities and outcomes that they cannot influence; and

- Provides dialysis facilities with sufficient flexibility to meet the individual needs of each patient.

I. KCP supports the shift to a patient-centered set of Conditions for Coverage because it emphasizes the importance of patient outcomes over process.

KCP applauds CMS's decision to focus on the quality of care patients on dialysis receive. We are particularly pleased that the agency has placed a new emphasis on patient satisfaction, outcomes, patient assessments, plans of care, and patient education. For example, we support the Conditions for Quality Assessment and Performance Improvement, as well as the adoption of the Centers for Disease Control and Prevention and the Association for the Advancement of Medical Instrumentation guidelines related to infection control and water quality and purity, respectively. We are also encouraged by the fact that CMS recognizes the need for better training of patient care dialysis technicians, but we are concerned that the proposed requirements are not sufficient in this area.

Ensuring high-quality care for patients with kidney disease remains the central focus of KCP. Our members have worked diligently to improve quality, as the ESRD Clinical Performance Measures Project recognized when it stated: "Since 1994, [we have] documented continued improvements, specifically in the areas of adequacy of dialysis and anemia management. The providers of dialysis services are to be commended for their ongoing efforts to improve patient care."[2]

Personnel Qualifications (§ 494.140(e)): One quality initiative that KCP strongly supports is the need for more consistent training for patient care dialysis technicians. As noted in the Proposed Rule, there are no federal requirements pertaining to the training of patient care dialysis technicians. 70 Fed. Reg. at 6222. KCP strongly supports efforts to establish uniform training and certification requirements for these technicians. This approach is consistent with that proposed in legislation introduced by Sens. Rick Santorum (R-PA) and Kent Conrad (D-ND) and Reps. Dave Camp (R-MI) and William Jefferson (D-LA). S. 635 and H.R. 1298 would require that patient care dialysis technicians receive uniform training and become certified,

[2]Centers for Medicare and Medicaid Services (CMS), 2003 Annual Report: ESRD Clinical Performance Measures Project 5 (2003).

indicating at least a minimum level of competency to provide dialysis-related services. These technicians would be required to repeat training or become recertified if 24 consecutive months pass during which they have not performed dialysis-related services. Service providers and renal dialysis facilities would provide performance reviews and in-service education to assure ongoing competency. Although KCP recognizes the importance of deferring to the states to regulate health care workers, the Medicare program has already established similar training requirements for unlicensed personnel in skilled nursing facilities. Given this, we urge CMS to modify the Proposed Rule to incorporate the training and certification requirements outlined in the legislation described above.

KCP supports on-the-job training of patient care technicians, but does not believe only RNs are capable of providing the necessary direct supervision. Historically, our members have successfully relied upon RNs, licensed practical nurses (LPNs), and experienced patient care technicians to train and mentor new patient care technicians. The Conditions for Coverage should recognize that any of these categories of health care workers are capable of providing various components of the training and mentoring of new patient care dialysis technicians. For example, in most cases, experienced patient care technicians can appropriately train and mentor new technicians if an RN has first assessed the learning needs of the trainee and appropriately delegated the training and mentoring to a qualified LPN or patient care technician. Allowing facilities to retain this flexibility would ensure that those providers within a dialysis facility who have the most experience in performing the specific tasks train and mentor new patient care technicians under the direct supervision of an RN. Therefore, KCP urges CMS to require that RNs *directly supervise* the training and mentoring of new patient care technicians, while delegating *immediate supervision* of these activities to qualified patient care technicians and LPNs. To ensure that the regulation clearly expresses these relationships, we also suggest that CMS define the term *direct supervise* to mean that the RN must be present in the dialysis facility and be immediately available to furnish assistance and direction throughout the performance of the training and mentoring activities; it does not mean the RN must be present in the room during the training and mentoring activities. CMS should also define the term *immediate supervision* to mean that the health care professional to whom the training and mentoring activities have been delegated is actually in the room with the new patient care technician and engaged in the training and mentoring activities.

Recommendation: KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it allows facilities to provide high-quality care to patients without imposing unnecessary burdens.

II. KCP is concerned that the extensive nature of the Proposed Rule will result in significant increases in costs for facilities at a time when, as MedPAC recognizes, facilities must subsidize the cost of care due to Medicare's longstanding under-funding of the ESRD program.

The ESRD composite rate is the only Medicare PPS without an annual update mechanism to adjust for changes in input prices and inflation. In its most recent report, MedPAC indicates that Medicare payments do not cover the costs dialysis facilities incur when caring for beneficiaries. The adequacy of Medicare payment has eroded during the past 20 years. Using 2005 dollars, the payment in 1983 was $134; today it is only $130.

The Proposed Rule is troubling because it would expand the scope of services dialysis facilities must provide without addressing the fact that dialysis facilities must subsidize the cost of care they provide to Medicare beneficiaries because of the failure of the Medicare program to appropriately fund the ESRD program. For example, it would require most facilities to install expensive new equipment for which the costs significantly outweigh the benefits the equipment would provide and would establish additional paperwork requirements that would duplicate what other providers already must do. KCP strongly urges CMS to review the Proposed Rule and eliminate those Conditions for Coverage that add significant costs to providing care for Medicare patients without directly providing benefits to patients, unless an annual update mechanism is established for the ESRD composite rate.

Physical Environment (§ 494.60): CMS's Proposed Rule would increase the costs facilities incur by requiring the installation of new equipment, the benefit of which is doubtful. For example, it would require dialysis facilities to install automatic notification systems that would alert emergency personnel of a fire. 70 Fed. Reg. at 6197-200 (§ 494.60). Although the idea has merit, KCP is concerned that the cost of implementing the system outweighs the potential benefit. Dialysis facility staff is always on-site monitoring patients, as well as their physical surroundings. In the case of fire or another type of emergency, they are trained to contact emergency personnel immediately and to work to ensure the safety of all patients.

This proposed Condition would require a significant investment by many dialysis facilities while providing questionable benefits. One KCP member investigated the cost of an automated notification system in the Orlando area. Installation alone would exceed $3000. Monitoring would cost each facility approximately $186 per month. CMS's calculation is much lower because the agency did not include the required back-up phone line that would cost approximately $106 per month. The agency's installation estimate is extremely low, based upon current market prices. Assuming a conservative estimate that only half of U.S. dialysis facilities would need to install new systems, the total cost of this provision alone would be close to $5

million. In addition, dialysis facilities are frequently located in buildings in which they rent space and are limited by the lease as to what remodeling they may do. Also, some facilities are located in buildings that if sprinkler systems must be installed, they will have to be installed in all parts of the building. In these instances, facilities would be forced to relocate and be subject to the additional costs associated with such moves. Because of the financial difficulties facilities already face, it simply does not make sense to require them to shift scarce resources away from patient care to install new systems that will not result in significantly better safety for patients.

Plan of Care (§ 494.90): Similarly, KCP questions the benefit of duplicating the transplant referral tracking already required of transplant centers. KCP agrees that there is value in documenting in a patient's record his/her transplant status as determined by a transplant center. 70 Fed. Reg. at 6207 (§ 494.90). It is a patient's treating nephrologist who has that responsibility and prerogative. Additionally, given the scarce resources available to dialysis facilities, it does not make sense to require dialysis facilities to communicate quarterly with transplant centers and to track each patient's transplant status. To the contrary, transplant centers are required to notify the dialysis facility of a patient's transplant status following referral through their own Conditions of Participation. 70 Fed. Reg. at 6161 (§482.94(c)). When a patient's status changes, the transplant center should contact the dialysis facility so that it can update the patient's records.

Given the existing financial constraints on dialysis facilities, it simply does not make sense to require facilities to take money that would otherwise go to patient care and spend it installing new equipment or mandating new administrative duties that will provide questionable benefits to patients.

Recommendation: KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it is cost effective and avoids placing significantly higher costs on facilities, especially if the benefit to patients is questionable.

III. KCP is concerned that some of the proposed Conditions for Coverage would inappropriately hold facilities responsible for activities and outcomes over which they do not have control.

KCP agrees that one of the primary objectives of the Conditions for Coverage should be to "establish performance expectations for facilities." 70 Fed. Reg. at 6184. Although we are pleased that CMS has proposed revisions that are more patient centered and encourage patients to take a more active role in their treatment, we are deeply concerned that some of the changes would establish performance expectations that dialysis facilities do not have sufficient personnel

resources or authority to influence. We are also concerned that the Proposed Rule would hold dialysis facilities responsible for the activities of other providers, such as nursing facilities, rehabilitation facilities, transplant centers, pharmacists, and attending nephrologists, over which dialysis facilities have no control. Simply put, it is not appropriate for CMS to judge dialysis facilities for activities that they cannot influence and control. Therefore, we strongly urge CMS to modify the Proposed Rule to focus on those aspects of patient care that dialysis facilities have the ability to influence or control.

Plan of Care (§ 494.90): One area of concern is the proposed Condition that would require dialysis facilities to "***provide*** the necessary care and service for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients." 70 Fed. Reg. at 6250 (§ 494.90) (emphasis added). KCP strongly believes patients on dialysis should remain as active and productive as possible. It is important that everyone in the kidney care community works to promote the physical and mental well being of patients.

The approach the agency proposes is problematic in this regard: as drafted, this proposed Condition seems to suggest that dialysis facilities are required to provide comprehensive rehabilitation care, which is outside of the specialized training of dialysis facility staff and beyond the scope of payment for dialysis services. KCP agrees that social workers should provide assessments and guidance to patients to help them understand better how to alter their lifestyles and work with other health care providers to increase their level of productive activity. Dialysis facilities and their staff can and should serve as a safety net for monitoring patient well-being and guiding patients in a way that allows them obtain the highest quality of life. However, the general language of the proposed Condition appears to require facilities to do much more than that. Given the current Medicare reimbursement rates, dialysis facilities cannot afford to hire rehabilitation specialists to provide comprehensive care. Rather than mandate that dialysis facilities ***provide*** this type of care, KCP strongly urges CMS to modify this Condition so that dialysis facilities are required to document that the social worker and facility staff have discussed with patients whether to seek referrals from their nephrologists for additional rehabilitation services (such as physical therapy, occupational therapy, counseling, and vocational rehabilitation).

The clearest example of how CMS could inappropriately hold dialysis facilities responsible for the activities of other providers over which they have no control is the proposed Condition to make dialysis facilities responsible for ensuring that each patient's physician sees the patient at least once a month. 70 Fed. Reg. at 6250 (§ 494.90(b)(4)). Nephrologists are not employees of dialysis facilities. They are independent providers and receive payments separate and apart from the reimbursement dialysis facilities receive. KCP feels strongly that because the

Conditions for Coverage are meant to ensure that dialysis facilities that participate in the Medicare program meet certain requirements to promote patient care and that failure to meet these requirements may result in exclusion from the Medicare Program, it is inappropriate and counterproductive to hold dialysis facilities responsible for the actions of other providers over which the facilities have no control. Additionally, this Condition appears to be an attempt to regulate nephrologists indirectly. The Social Security Act prohibits CMS from "exercis[ing] supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. It is inappropriate for CMS to try to regulate how nephrologists practice medicine through the ESRD Conditions for Coverage. For these reasons, we urge CMS to eliminate this requirement.

Care at Home (Preamble discussion of ESRD patients in nursing and skilled nursing facilities): In the preamble of the Proposed Rule, CMS suggests that it is considering how to address the issues raised by providing dialysis to the frail elderly residing in nursing and skilled nursing facilities. 70 Fed. Reg. at 6212-14. Given that CMS has yet to propose regulatory text to address these issues, KCP looks forward to working with the agency as it begins exploring how to deal with this unique ESRD subpopulation. In the meantime, we strongly encourage CMS to clarify that until the agency provides more nursing facility-specific guidance the institution in which the patient is living (*e.g.*, a nursing or skilled nursing facility) will be deemed to be the patients' "home" for purposes of ESRD regulations. Without this specific designation, there will continue to be significant confusion that threatens the quality of care these patients receive.

> ***Recommendation: KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it recognizes those activities and outcomes over which dialysis facilities are practically able to exercise control and does not hold them responsible for activities and outcomes that they cannot influence.***

IV. KCP is concerned that some of the proposed Conditions for Coverage are overly prescriptive and contrary to the goal of maximizing flexibility.

KCP appreciates CMS's efforts to revise the Conditions for Coverage to "provide greater flexibility" for dialysis facilities. *See* 70 Fed. Reg. at 6187. We strongly believe greater flexibility will allow facilities to focus more on the individual needs of patients and less on general procedural requirements. For the most part, the Proposed Rule takes important steps that allow for this increased flexibility. However, KCP is concerned that the agency has not incorporated the need for flexibility into some of the Conditions. One example of this problem is the timeline

the agency proposes for conducting the patient assessment and establishing each patient's individualized plan of care.

Patient Assessment and Plan of Care (§§ 494.80 & 494.90): The proposed patient assessment and plan of care timelines lack sufficient flexibility because they inappropriately focus on calendar days rather than on the number of visits patients make to a facility. 70 Fed. Reg. at 6203-10 (§§ 494.80 & 494.90). KCP agrees that patients should receive assessments and plans of care in a timely manner. However, by focusing on calendar days, rather than on the number of patient treatments in the facility, CMS ignores the reality that a patient may not receive treatments from a single dialysis facility during the first months of dialysis due to the patient's unstable condition and need for re-hospitalization.

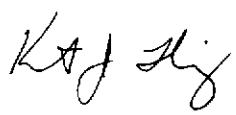
Because of this reality, KCP suggests that CMS modify the Proposed Rule to require that facilities have (1) ***9 consecutive treatment sessions*** during which to complete patients' assessments and that reassessments for new patients occur within ***36 treatment sessions*** after the completion of the initial assessment and (2) ***5 treatment sessions*** after the initial assessment is complete to develop and implement the plan of care. These timelines correspond to the timelines set forth by CMS, but give providers the flexibility to adjust for individual patient needs.

> ***Recommendation: KCP strongly encourages CMS to review carefully each proposed Condition to ensure that it provides dialysis facilities with sufficient flexibility to meet the individual needs of each patient.***

V. Conclusion

Generally, KCP is pleased that CMS has published proposed Conditions for Coverage that recognize the importance of focusing on patient care. As the agency continues to consider how to modify the Conditions, our members would welcome the opportunity to meet with you and your staff to discuss these comments.

Sincerely,



Kent J. Thiry
Chairman of the Board
Kidney Care Partners

Attachment A

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Nephrology Nurses Association
American Regent, Inc.
Amgen
Baxter Healthcare Corporation
Bone Care International
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Fresenius Medical Care North America
Gambro Healthcare/USA
Genzyme
Medical Education Institute
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Physicians Dialysis, Inc.
Renal Care Group
Renal Physicians Association
Renal Support Network
Satellite Health Care
Sigma-Tau Pharmaceuticals, Inc.
Watson Pharma, Inc.

Bone Care
INTERNATIONAL

Bone Care Center 1600 Aspen Commons Middleton, WI 53562 Phone: (608) 662-7800 Fax: (608) 662-0032

May 5, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments to CMS-3818-P: Medicare Program – Conditions of Coverage for End Stage Renal Disease Facilities

Dear Administrator McClellan:

Bone Care International, Inc. (Bone Care) submits these comments regarding the Proposed Rule (CMS-3818-P) titled "Medicare Program: Conditions of Coverage for End Stage Renal Disease Facilities" to the Centers for Medicare & Medicaid Services (CMS). Bone Care is a specialty pharmaceutical company engaged in the discovery, development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Our current commercial and therapeutic focus is in nephrology, utilizing Hectorol®, a novel D pro-hormone therapy to treat secondary hyperparathyroidism in patients with moderate to severe Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD).

We first want to thank CMS for its commitment to modernizing the regulatory framework and its focus on improving quality of care and the efficient delivery of appropriate medical treatments. In particular, we commend CMS for its plan to reform the ESRD regulations such that they will be (1) "Founded on evidence"; (2) "Be patient-centered"; (3) "Promote outcomes desired for Medicare and Medicaid beneficiaries as well as others served by participating ESRD suppliers of services"; (4) "Establish a framework for the collection and reporting of consensus-driven performance standards"; (5) "Set clear expectations for dialysis facility accountability"; and (6) "Stimulate improvements in processes, outcomes of care, and beneficiary satisfaction."[1] We absolutely agree with CMS's plan to focus these regulations on patients' needs and improvement of outcomes.

[1] See 70 Fed. Reg. 6184, 6185.

At the same time, we feel CMS could improve upon the Proposed Rule in multiple areas. In these comments, we urge CMS to: (1) require assessment and treatment of bone and mineral metabolism and imbalances in calcium/phosphorus/PTH/Vitamin D in accordance with the National Kidney Foundation-Dialysis Outcomes Quality Initiative (K/DOQI) guidelines as part of the Patient Plan of Care; (2) adopt its proposal to require assessment of factors associated with bone disease as part of each patient's comprehensive assessment; (3) require a pharmacist's participation on the interdisciplinary team; and (4) create a condition of participation for ESRD facilities that ensures appropriate drug therapy for secondary hyperparathyroidism in accordance with CMS's acknowledgement of the need for such a requirement.[2]

I. Preamble: National Kidney Foundation Guidelines

Bone Care applauds CMS's development of dialysis Clinical Performance Measures (CPMs) based on the K/DOQI guidelines and for proposing the adoption of certain guidelines based on the K/DOQI, such the guideline for anemia management, as facility requirements in the Proposed Rule. As CMS notes in the Preamble, requiring facility reporting of compliance with guidelines that were the culmination of the K/DOQI process has already proven to improve the quality of care provided to dialysis patients.

The standard treatment of secondary hyperparathyroidism in stage 5 CKD is implementation of K/DOQI recommendations for the control of calcium, phosphorus, and parathyroid hormone (PTH) using D hormone therapies.[3] We believe CMS should require assessment and treatment of bone and mineral metabolism and imbalances in calcium/phosphorus/PTH/Vitamin D in accordance with the K/DOQI guidelines. Specifically, CMS should include such an assessment and treatment plan as an element of the required Patient's Plan of Care (Proposed Section 494.90). Requiring a Patient's Plan of Care to address not only ESRD and anemia but also secondary hyperparathyroidism is supported by the prevalence of secondary hyperparathyroidism in the ESRD patient population, the significance of the deleterious effect of the disease on patients and the clinical consensus regarding the benefit of D hormone treatments.

II. Proposed Section 494.80: The Evaluation of Bone Disease

Proposed Section 494.80 includes the "evaluation of factors associated with renal bone disease" as an element of a patient's comprehensive assessment, which a dialysis facility would be required to perform to participate in the Medicare program. We strongly support the inclusion of an assessment of renal bone disease indicators as part of the minimum set of assessment criteria because of the importance of treating renal bone disease in the ESRD patient population.

A significant percentage of patients with ESRD suffer from secondary hyperparathyroidism. As the kidney fails, it produces diminishing amounts of active D hormone. This, in turn, results in less calcium being absorbed into the body. When serum calcium levels

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[2] See 69 Fed. Reg. 66236, 66321 (November 15, 2004).

[3] Classical vs. Non-Classical Activity of Vitamin D. Medfacts. Vol.7, No. 1, (January) 2005.

fall below the normal range, the parathyroid gland releases increased amounts of PTH. The increased concentrations of PTH result in the reabsorption of calcium from the bone, a condition known as secondary hyperparathyroidism. Left untreated, secondary hyperparathyroidism can eventually result in multiple co-morbid conditions, including cardiovascular compromise, reduced immunity, muscle weakness, bone loss and/or fractures.

Of course, bone disease seriously compromises the ability of a dialysis patient to manage his/her disease and treatment by negatively affecting the patient's mobility and availability for treatment. We echo CMS's comments in the Proposed Rule that requiring a detailed assessment of a patient's condition, including the patient's risk of bone disease is essential to promoting better treatment plans and outcomes.

III. Proposed Section 494.80: Need for a Pharmacist's Participation in Patient Care

Proposed Section 494.80 also strengthens the current requirement for patient consultations by establishing an interdisciplinary team that will develop and review a patient's individualized, comprehensive care plan based on the comprehensive assessment.[4] We support this provision and believe an interdisciplinary team that includes not only a registered nurse, a physician, a social worker, and a registered dietitian, but also a pharmacist, which is missing from CMS's proposal, will help achieve the well-rounded team that can best assess an individual patient's needs and allow for planning for necessary services.

For ESRD patients, the inclusion of a pharmacist in the interdisciplinary team will be critical in effective drug management. Patients with ESRD often have high co-morbidities and complicated drug regimens. The Dialysis Outcomes and Practice Patterns Study (DOPPS) has observed in their large retrospective database of ESRD patients that, on average, patients take nine drugs per day (range four to eighteen per patient per day). A pharmacist's expertise in overseeing complicated medication therapy will help protect such patients from drug interaction problems and adverse drug events. Among other conditions, we believe that including a pharmacist on the interdisciplinary team will help ensure effective treatment of secondary hyperparathyroidism, a disease that affects more than 65% of the ESRD patient population.

IV. Section 494.100: Assurance of Appropriate Drug Treatments

As acknowledged by CMS in the 2005 Final Physician Fee Schedule, current reimbursement of separately payable ESRD drugs may have the unintended effect of discouraging dialysis facilities from providing the full range of necessary drug treatments for ESRD patients.[5] While Bone Care strongly supports CMS's statements regarding the

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[4] See 70 Fed. Reg. at 6212.

[5] Specifically, CMS stated that:

> [o]ne comment from a patient organization raised concern the add-on provision would remove any incentives the current payment policy creates for facilities to provide separately billable drugs and biologicals to dialysis patients. ....
> Response: We share this commenters concern that changes in payments to dialysis facilities could produce perverse incentives for dialysis facilities to skimp on care to ESRD patients. In order to ensure that patients continue to receive quality care, we are revising the ESRD facility conditions

responsibility of ESRD facilities to ensure that adequate care is provided in the context of nursing homes,[6] we urge CMS to require adequate drug therapy for specific conditions associated with dialysis, such as secondary hyperparathyroidism, as a condition of Medicare reimbursement to dialysis facilities and to follow the many precedents for analogous conditions of participation that exist elsewhere in the Medicare program.

As recognized in the K/DOQI clinical practice guidelines, an extremely common condition among dialysis patients is secondary hyperparathyroidism. There is strong medical consensus that D hormones are critical in treating this condition (as evidenced by the National Kidney Foundation's K/DOQI Guidelines).[7] Additionally, scientific evidence suggests that treating secondary hyperparathyroidism improves clinical outcomes and may reduce mortality and morbidity in patients with CKD and limit the costs of treating CKD as a whole. Moreover, there is evidence suggesting that treatment of this disorder improves quality of life and provides greater potential for rehabilitation and return to or continued employment, with a greater degree of independence. Therefore, any standards adopted by CMS should require that dialysis facilities provide access to treatments with D hormones whenever necessary.

Physicians and dialysis providers favor intravenous products for the treatment of secondary hyperparathyroidism in Stage 5 CKD patients on hemodialysis for a number of important reasons. First, healthcare professionals can assure patient adherence with drug administration at the time of dialysis. Second, administration allows for close monitoring of the response to treatment and appropriate dose adjustments to better achieve outcomes.

Any quality standard adopted by CMS should place a premium on D hormone therapies that mimic the normal physiologic action of active D hormones by normal kidneys. Normal physiologic blood levels of D-hormones allow efficient regulation of PTH secretion by the parathyroid glands with few side effects.

There are numerous precedents for taking such action. For instance, the Long Term Care Facility conditions of participation require that "[t]he facility must provide routine

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for coverage so that they are more patient-centered and outcome-oriented.

See 69 Fed. Reg. 66236, 66321 (November 15, 2004).

[6] The Preamble of the Proposed Rule states that "[w]e believe that the ESRD facility should -- (1) periodically assess the ability of the staff (NF or SNF staff and caregiver) responsible for care of the ESRD patient to assure that they are competent in their tasks; (2) retrieve and review complete data, including laboratory data, clinical data, outcome data, and interdisciplinary team notes *to assure that adequate care is being provided*; (3) monitor the care of the patients, using appropriate clinical standards...." See 70 Fed. Reg. 6184, 6214 (emphasis added).

[7] National Kidney Foundation K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease, Am. J. Kidney Dis. 42:S1-S202, 2003 (suppl3).

There are two principal forms of D hormones – active and inactive. Inactive D products (e.g., ergocalciferol and cholecalciferol) are used as vitamin supplements and are sold over the counter without a prescription. There are three forms of active D – doxercalciferol, calcitriol, and paricalcitrol.

In order for inactive vitamin D to affect tissues, it must be converted in the liver and kidneys into an active form. Because the endocrine kidney function of CKD patients is impaired, only active forms of D, which do not require biologic activation in the kidneys, can be used to treat secondary hyperparathyroidism.

and emergency drugs and biologicals to its residents, or obtain them under an agreement . . . ."[8] Furthermore, they require that "[a] drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner." See id. Additionally, facilities are required to provide pharmaceutical services to meet the needs of each resident.[9]

Moreover, CMS and many payors have begun to implement "pay for performance" programs that provide reimbursement for the provision of quality care or data. Under the Medicare Modernization Act, hospitals receive a full inflationary increase in 2005 only if they provide data on certain measures of the quality of care they deliver. CMS is also engaged in a "pay for performance" demonstration with Premier in which hospitals that perform in the top 10% based on clinical quality measures receive bonuses.

We believe that further specification requiring ESRD facilities to provide all necessary drug treatment to dialysis patients, including treatments for secondary hyperparathyroidism, is necessary to offer meaningful protection to ESRD patients against inadequate care. Requiring access to therapeutic drug treatment will not only avoid negative and unacceptable outcomes, but will likely translate into higher quality of care for ESRD patients.

* * *

Thank you for your consideration of these comments. Please let us know if you have any questions. We are happy to discuss any aspect of our comments with you at your convenience.

Sincerely,

C. Basil Mundy
Vice President, Government Affairs and
Corporate Relations

cc: William A. Sarraille, Sidley Austin Brown & Wood, LLP
Anna L. Spencer, Sidley Austin Brown & Wood, LLP

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[8] See 42 CFR §483.50.

[9] See 42 CFR §483.60(a). Similar requirements are found in conditions of participation for Hospitals, Hospice and Intermediate Care Facilities for the Mentally Retarded. See 42 CFR §§418.96 and 483.460(i). The Hospital conditions of participation state as follows:

> [p]rovision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

See 42 CFR §482.25.

Roche

May 5, 2005

SUBMITTED ELECTRONICALLY & BY HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3818-P (Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities)

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche") submits the following brief comments in response to the proposed rule revising the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare program.[1] Roche, based in Nutley, New Jersey, is the U.S. prescription drug unit of Roche Group, a research-based health care company that ranks among the world's leading manufacturers of pharmaceutical and diagnostic products. Roche provides innovative products that enhance public health and quality of life by preventing and treating diseases and disorders. Roche currently manufactures, or is actively developing, medical products to treat persons with kidney disease and kidney transplant patients. We appreciate the opportunity to provide comments on this rule.

Pursuant to the instructions included in the Notice of Proposed Rulemaking, each comment is set forth under a caption referencing the section of the proposed rule to which that comment relates.

Patient Assessment

The proposed ESRD facility conditions of coverage are focused on patient outcomes, and Roche strongly supports this approach. We also support the proposed requirement that dialysis facilities prepare a comprehensive needs assessment for each new dialysis patient and evaluate the factors associated with anemia as part of that assessment (proposed §494.80). Further, we agree with establishing timeframes for conducting those assessments, as well as the requirement that patients with unmanaged anemia be comprehensively re-assessed on a monthly basis.

We note that CMS did not define what constitutes "unmanaged anemia" for an ESRD patient, and we suggest that CMS clarify this in the final rule. Patient hemoglobin and hematocrit levels can fluctuate around the target over a given time period, which presents a medical

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1 70 Fed. Reg. 6184 (February 4, 2005).

management challenge for caregivers. In setting the standard for "unmanaged anemia," we recommend that CMS avoid setting a specific numerical target in the coverage conditions and instead have the conditions defer to the most recently updated NKF-K/DOQI Anemia Guidelines, which is consistent with the proposed requirements with respect to the patient care plan (discussed below), as well as any other relevant practice guidelines that may be developed and issued in the future. Practice guidelines are intended to be an aid to practitioners, allowing them to remain at the forefront of quality care. If the standard for "unmanaged anemia" is based on the most recently updated clinical guidelines, CMS will ensure that the standard set forth in the coverage conditions reflects the most up-to-date clinical recommendations available, without the Agency having to go through a burdensome rulemaking process each time the clinical standard is updated.

Plan of Care

Roche supports CMS' proposed requirement that facilities develop patient care plans that include measurable and expected outcomes based on accepted clinical practice guidelines, such as the NKF-K/DOQI guidelines, and estimated timetables for achieving these outcomes (proposed §494.90). We also agree that with respect to anemia management, patient hemoglobin/hematocrit levels should be measured at least monthly, and that the facility must conduct an evaluation to determine whether the patient is a candidate for erythropoietin based on the most current recommended clinical guidelines, which currently provide that a patient is a candidate if he or she has a hemoglobin less than 11 gm/dL or hematocrit of less than 33 percent. Roche also supports requiring facilities to include the standard in the most recent NKF-K/DOQI Guidelines as the minimum threshold value for anemia management in a patient's care plan, as well as requiring facilities to update their plans of care within an acceptable timeframe when relevant clinical guidelines are updated.

We note that although we agree with using the standards set forth in the most recent NKF-K/DOQI guidelines, it is possible that the clinical guidelines may not be revised in time to promptly incorporate the latest medical research in appropriate treatments for patients with ESRD. We recommend that CMS provide leadership in this area and as promptly as possible incorporate into the ESRD conditions of coverage the latest clinical developments for ESRD that are supported by strong, direct evidence. Particularly with respect to evidence-based, ground-breaking innovations which will likely incur a delay before they are incorporated into the NKF-K/DOQI guidelines, CMS has an opportunity and a responsibility to show strong leadership and vision, which will aid in improving patient outcomes.

Governance

We endorse CMS' proposal to require all dialysis facilities to furnish data on all patients as part of the ESRD Clinical Performance Measures (CPM) project. Roche agrees that requiring facilities to report data on the adequacy of dialysis, anemia management, serum albumin, and vascular access management will help the Agency better evaluate and monitor facilities to ensure the necessary services are being provided, as well as help patients evaluate dialysis providers and make better choices about where to access their care. Although we endorse CMS' decision to post on the Dialysis Facility Compare website the percent of patients treated in an ESRD facility with a $Kt/V \geq 1.2$, and the percent of patients with hemoglobin levels within the targets recommended in the latest NKF-K/DOQI guidelines, we encourage CMS to post other relevant laboratory values in addition

to those measuring the facility's performance in the area of dialysis adequacy and anemia management.

Conclusion

Roche appreciates the opportunity to submit comments to CMS regarding the proposed conditions of coverage for dialysis facilities. We look forward to working with CMS in the future on issues related to quality of care for ESRD patients.

Respectfully submitted,

Michael J. Eging
Executive Director
Public Policy and Federal Government Affairs

Melissa Fry, CAPSW, MSW Comment on
Conditions for Coverage for End Stage Renal Disease Facilities File code CMS-3818-P

LOCATION OF COC

PROPSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/05-1622.pdf	
494.70 Condition Patients' Rights (a) Standard: Patients' Rights	***Add***: (new 17) "Have access to a qualified social worker and dietitian as needed" ***Rationale:*** Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed. ***References:*** Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht,
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies	***Add***: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it canbe shown that the patient's behavior is putting other patients or the facility operations at risk." ***Rationale:*** The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis. ***References:*** Forum of ESRD Networks,2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Change***: (renumbered 3) Delete or define "reducing...ongoing care." ***Rationale:*** This phrase is unclear.
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Add***: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation." ***Rationale***: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be

	as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Comment:*** I support the language of a2, a3, a4, a5, a6 ***Change***: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)." ***Rationale***: Elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response. ***Comment:*** I support the language of a8
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients.	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. ***Comment:*** I support the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment.	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess ***Add***: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale***: Low PCS scores predict higher morbidity and mortality in research among ESRD patients. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." ***Rationale***: Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments.

	References: DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vii) "Depression per patient report, staff observation or validated depression screening survey" ***Rationale***: Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death. ***References:*** Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005 ***Add***: (new viii) "Loss of or threatened loss of employment per patient report" ***Rationale***: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. ***References:*** Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004; Witten, Schatell & Becker, 200
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking.	***Comment:*** I support the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant
NEW CONDITION Staff assisted skilled nursing home dialysis	***Add:*** A newcondition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:*** Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis

	patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of the proposed conditions of coverage
494.140 Condition Personnel qualifications.	***Comment:*** I recommend that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). I suggest possible responsibilities for social workers in the next section, where we comment on "494.140 ConditionPersonnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section. ***Rationale & References***: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination of benefit periods. • 44% of social workers were primarily responsible for completing patient admission paperwork. • 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship). • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients.

	• Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, I am strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section)
494.140 Condition Personnel qualifications (d) Standard: Social worker.	***Change the language of d to***: *Social worker*. The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks. ***Rationale & References***: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by me for the transplant conditions of coverage. I support the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition. Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and

utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above. It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003).

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access

	to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
494.140 Condition Personnel qualifications.	***Add***: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage. ***Rationale & References***: We agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should <u>not</u> be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, <u>End-Stage Renal Disease Workgroup Recommendations to the Field</u>, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination periods. • 44% of social workers were primarily responsible for completing admission packets. • 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust. • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs.

	This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, I recommend a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide
494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing). Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients. In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59). Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios): • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and

education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.

- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression.

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment

REFERENCES

ADA, Title III, Part 36, Subpart A, Section 36.303, auxiliary aids (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-97857)

ADA Title III, Part 36, Subpart A, Section 36.304, removal of barriers (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-91481)

Anderson, R. (1986). The CSWE Accrediting Standards for Social Work Education. *Social Work in Education*. CCC Code: 0162-7961/86.

Andreucci, V. E., et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) data onmedications in hemodialysis patients. *Am J Kidney Dis.* 44(5 Suppl 3):61-7, 2004.

Auslander, G. K., Buchs, A. (2002). Evaluating an activity intervention with hemodialysis patients in Israel. Social Work Health Care. 35(1-2):407-23.

Auslander, G., Dobrof, J., & Epstein, I. (2001). Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. *Social Work in Health Care*, 33(3/4), 129-151.

Beder, J. (1999). Evaluation research on the effectiveness of social work intervention on dialysis patients: the first three months. *Social Work in Health Care*, 30(1), 15-30.

Beder, J., Mason, S., Johnstone, S., Callahan, M. B., & LeSage, L. (2003). Effectiveness of a social work psychoeductional program in improving adherence behavior associated with risk of CVD in ESRD patients. *Journal of Nephrology Social Work*, 22, 12-22.

Blake C, Codd MB, Cassidy A, O'Meara YM. Physical function, employment and quality of life in end-stage renal disease. *J Nephrol.* 13(2):142-9, 2000.

Bogatz, S., Colasanto, R., & Sweeney, L. (2005). Defining the impact of high patient/staff ratios on dialysis social workers. *Nephrology News & Issues*, Jan, 55-60.

Bonner, C., Dean, R., & Greenspan, R. (1989) Standards for Practice: The Development of the Clinical Social Worker in the First Two Years. *The Clinical Supervisor* 1989. 7(4), 31-45.

Booz, A., & Hamilton, Inc. (1987) *The Maryland Social Work Services Job Analysis and Personnel Qualifications Study*. Prepared for the Department of Human Resources State of Maryland

Burrows-Hudson, S. (1995). Mortality, morbidity, adequacy of treatment, and quality of life. *ANNA Journal*, 22(2), 113-121.

Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M. (1998). Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. *Journal of Nephrology Social Work*, 18, 66-79.

Callahan, M. B., Witten, B., & Johnstone, S. (1997). Improving quality of care and social work outcomes in dialysis. *Nephrology News & Issues*, 2(4), 42-43.

Chang, C. F., Winsett, R. P., Gaber, A. O., & Hathaway, D. K. (2004) Cost-effectiveness of post-transplantation quality of life intervention among kidney recipients, *Clinical Transplantation*, 18(4), 407-415.

Coulton, C. (1979). A study of the person-environment fit among the chronically ill. *Social Work in Health Care*, 5(1), 5-17.

Council on Social Work Education: Commission on Accreditation, *Handbook of Accreditation Standards and Procedures* (Fourth Edition). Subsection B5.7.9 and M5.7.11 and Subsection B5.7.7 and M5.7.8, pp. 99, 137.

Curtin RB, Oberley ET, Sacksteder P, Friedman A. (1996). Differences between employed and non employed dialysis patients. *Am J Kidney Dis.* 27(4):533-40.

Curtin RB, Mapes DL. (2001) Health care management strategies of long-term dialysis survivors.*Neph Nurse J.* 28(4):385-394.

Curtin RB, Bultman DC, Schatell D, Chewning BA. (2004) Self-management, knowledge, andfunctioning and well-being of patients on hemodialysis. *Neph Nurs J* 31(4):378-387.

Curtin RB, Bultman DC, Thomas-Hawkins C, Walters BA, Schatell D. Hemodialysis patients' symptom experiences: effects on physical and mental functioning. *Nephrol Nurs J.*;29(6):562, 567-74; discussion 575, 598, 2002.

Curtin RB, Klag MJ, Bultman DC, Schatell D. Renal rehabilitation and improved patient outcomes in Texas dialysis facilities. Am J Kidney Dis.;40(2):331-8, 2002.

Curtin RB, Sitter DC, Schatell D, Chewning BA. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Nephrol Nurs J* 31(4):378-86, 396; quiz 387, 2004.

DeOreo, P. B. (1997). Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *American Journal of Kidney Diseases*. 30(2), 204-212.

Devins, G. M., Mandin, H., Hons, R. B., Burgess, E. D., Klassen, J., Taub, K., Schorr, S., Letourneau, P. K., & Buckle, S. (1990), Illness intrusiveness and quality of life in end-stage renal disease: comparison and stability across treatment modalities. *Health Psychology*, 9(2), 117-142.

Dhooper, S., Royse, D., & Wolfe, L. (1990) Does social work education make a difference? *Social Work Education,* 1990, 35 (1), 57-61.

Dobrof, J., Dolinko, A., Lichtiger, E., Uribarri, J., & Epstein, I. (2001) Dialysis patient characteristics and outcomes: the complexity of social work practice with end-stage renal; disease population. *Social Work in Health Care*, 33, 105-128.

Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf)

Frank, A., Auslander, G. K., & Weissgarten, J. (2003). Quality of life of patients with end-stage renal disease at various stages of the illness. *Social Work in Health Care*, 38(2), 1-27.

Gudes, C. M. (1995). Health-related quality of life in end-stage renal failure. *Quality of Life* ESRD Network of Texas (2002). Social Services Practice Recommendations.
http://www.esrdnetwork.org/professional_standards.htm

Holley, J. L., Barrington, K., Kohn, J., & Hayes, I. (1991). Patient factors and the influence of nephrologists, social workers, and nurses on patient decisions to choose continuous peritoneal dialysis. *Advances in Peritoneal Dialysis*, 7, 108-110.

Johnstone, S. (2003). Evaluating the impact of a physical rehabilitation program for dialysis patients. *Journal of Nephrology Social Work*, 22, 28-30.

Johnstone, S. & Halshaw, D. (2003) Making peace with fluid social workers lead cognitive-behavioral intervention to reduce health-risk behavior. *Nephrology News & Issues* (12), 20-31.

Johnstone, S., Seamon, V. J., Halshaw, D., Molinair, J., & Longknife, K. (1997). The use of medication to manage patient-staff conflict in the dialysis clinic. *Advances in Renal Replacement Therapy*, 4(4), 359-371.

Johnstone, S., Walrath, L., Wohlwend, V., & Thompson, C. (2004). Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. *Advances in Chronic Kidney Disease*, 11(2), 210-216.

Juhnke, J & Curtin, R.B. (2000) New study identifies ESRD patient education needs. *Nephrology News & Issues*14(6):38-9.

Kalantar-Zadeh, K., Kopple, J. D., Block, G., & Humphreys, M. H. (2001). Association among SF36 quality-of-life measures and nutrition, hospitalization, and mortality in hemodialysis. *Journal of the American Society of Nephrology*, 12, 2797-2806.

Kaitelidou, D., Maniadakis, N., Liaropouls, L., Ziroyanis, P., Theodorou, M., & Siskou, O. (2005). Implications of hemodialysis treatment on employment patterns and everyday life of patients. *Dialysis & Transplantation,* 34(3), 138-147, 185.

Katon, W., & Schulberg, H. (1997). Epidemiology of depression in primary care. *General Hospital Psychiatry,*14, 237-247.

Kaveh K & Kimmel PL. (2001). Compliance in hemodialysis patients: multidimensional measures in search of a gold standard. *American Journal of Kidney Diseases* 37(2):244-66.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D., Verne, D., Alleyne, S., & Cruz, I. Veis, J (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International*, 5(10), 2093-2098.

Kimmel, P., Peterson, R., Weihs, K., Simmens, Alleyne, S., Cruz, I., & Veis, J (1998). Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. *Kidney International*, 54, 245-254.

Kimmel PL et al Survival in hemodialysis patients: the role of depression. *J Am Soc Nephrol.* 4(1):12-27, 1993.

King K, Moss AH. The frequency and significance of the "difficult" patient: The nephrology community's perceptions. *Adv Chronic Kidney Dis.* 2004 Apr;11(2):234-9.

Knight EL et al. The association between mental health, physical function, and hemodialysismortality. *Kidney Int.* 63(5):1843-51 2003.

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 41(11):1284-92, 2003.

Kutner NL et al. Functional impairment, depression, and life satisfaction among olderhemodialysis patients and age-matched controls: a prospective study. *Arch Phys Med Rehabil*. 81(4):453-9, 2000.

Levenson, J., & Olbrisch, M. (2000). Psychosocial screening and candidate selection. In P. Trzepacz & A. DiMartini (Eds.), *The transplant patient: biological, psychiatric, and ethical issues in organ transplantation* (pp. 21-41). Cambridge: Cambridge University Press.

Lowrie EG, Curtin RB, LePain N, Schatell D. Medical outcomes study short form-36: aconsistent and powerful predictor of morbidity and mortality in dialysis patients. *Am J Kidney Dis*. 41(6):1286-92, 2003.

Mapes, D., Bragg-Gresham, J. L. Bommer, J. Fukuhara, S., McKevitt, P., & Wikstrom, B (2004). Health-related quality of life in the dialysis outcomes and practice patterns Study (DOPPS) American Journal of Kidney Diseases, 44 suppl(5), 54-60.

Mayo K. (1999)Can evening dialysis services improve the chances of rehabilitation? A Network #7 study. *Nephrol News Issues*. 13(6):37-8.

McKinley, M., & Callahan, M.B. (1998). Utilizing the case management skills of the nephrology social worker in a managed care environment. In National Kidney Foundation (Ed.), *Standards of practice for nephrology social work, 4th ed*, (pp. 120-128). NY: National Kidney Foundation.

McLaughlin K, Manns B, Mortis G, Hons R, Taub K. (2003). Why patients with ESRD do not select self-care dialysis as a treatment option. *Am J Kidney Dis*. 41(2):380-5.

Merighi, J. R., & Ehlebracht, K. (2005). Emotional Exhaustion and Workload Demands in Renal Social Work Practice, *Journal of Nephrology Social Work*, 24, 14-20, *Journal ofNephrology Social Work*, in press

Merighi, J. R., & Ehlebracht, K. (2004a). Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. *Nephrology News & Issues*, 18(4), 58-63.

Merighi, J. R., & Ehlebracht, K. (2004b). Issues for renal social workers in dialysis clinics in the United States. *Nephrology News & Issues*, 18(5), 67-73.

Merighi, J. R., & Ehlebracht, K. (2004c). Unit-based patient services and supportive counseling. *Nephrology News & Issues*, 18(6), 55-60.

Morrow-Howell, N. (1992). Clinical case management: the hallmark of gerontological social work. *Geriatric Social Work Education*, 18, 119-131.

National Association of Social Workers (1981) *Standards for the classification of social work practice.* Maryland: National Association of Social Workers.

Promoting Excellence in End-of-Life Care (2002), *End-Stage Renal Disease Workgroup Recommendations to the Field,* Missoula, MT: The Robert Wood Johnson *Protecting the Privacy of Patients' Health Information*(http://www.hhs.gov/news/facts/privacy.html)

Rasgon SA, Chemleski BL, Ho S, Widrow L, Yeoh HH, Schwankovsky L, Idroos M, Reddy CR, Agudelo-Dee L, James-Rogers A, Butts E. (1996). Benefits of a multidisciplinary predialysis program in maintaining employment among patients on home dialysis. *Adv Perit Dial*. 12:132-5.

Rabin, P. L. (1983). Psychiatric aspects of end-stage renal disease: diagnosis and management. In W. J. Stone & P. L. Rabin (Eds.) *End-Stage renal disease: an integrated approach, (*pp. 111-147). NY: Academic Press.

Rasgon, S., Schwankovsky, L., James-Rogers, A., Widrow, L., Glick, J., & Butts, E. (1993). An intervention for employment maintainence among blue-collar workers with end-stage renal disease. *American Journal of Kidney Diseases*, 22(3), 403-412.

Rau-Foster M. The dialysis facility's rights, responsibilities, and duties when there is conflict with family members. *Nephrol News Issues*. 15(5):12-4, 2001.

Renal Physicians Association and American Society of Nephrology. *Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis*

Rosen, L. S. (1999). Common psychosocial factors in the treatment of end stage renal disease. *Journal of Nephrology Social Work*, 19, 69-72.

Russo, R. (2002). The role of the renal social worker in the 21st century. *Nephrology News & Issues*, 16(3), 38,40.

Rubin, H., Jenckes, M., Fink, N., Meyer, K., Wu, A., Bass, E., Levin, N., & Powe, N. (1997). Patient's view of dialysis care: development of a taxonomy and rating of importance of different aspects of care. *American Journal of Kidney Disease*, 30(6), 793-801.

Siegal, B., Witten, B., Lundin, A.P (1994). Patient access and expectations of nephrology social workers. *Nephrology News and Issues*, April, 32-33,40.

Sikon, G. M. (2000). Pre-dialysis education reduces anxiety in the newly diagnosed chronic renal failure patient. *Dialysis & Transplantation*, 6, 346, 344-345.

Tong E. M. & Nissenson, A. R. (2002). Dialysis in nursing homes. *Seminars in Dialysis*. 15(2):103-6.

Vourlekis, B., & Rivera-Mizzoni, R. (1997). Psychosocial problem assessment and ESRD patient outcomes. *Advanmces in Renal Replacement Therapy,* 4(2), 136-144.

Wallace, S., Goldberg, R., & Slaby, A. (1984). *Guide for clinical social work in health care*. NY: Praeger Publishers.Witten B, Howell P, Latos D. (1999). Improving employment outcomes: the renal care team's role. *Nephrol News Issues*. 13(3):46-8.

Witten B, Schatell DR, Becker BN. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) *J Am Soc Nephrol.* 2004; 15:633A.

Wuerth D, Finklestein SH, Finklestein FO. The identification and treatment of depression in patients maintained on dialysis. *Semin Dial*. 18(2):142-6, 2005

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Renal Care Group

May 2, 2005

CMS
Department of Health and Human Services
Attn: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: Comments to the revised Conditions of Coverage for ESRD Facilities

Enclosed are my comments on the revised Conditions of Coverage and three attachments to support some of my comments. I have also had the opportunity to review comments being submitted by the NKF Council of Nephrology Social Workers, Kidney Care Partners and the Life Options Rehabilitation Program and support their comments as well.

Thank you for this opportunity to submit public comment.

Sincerely,

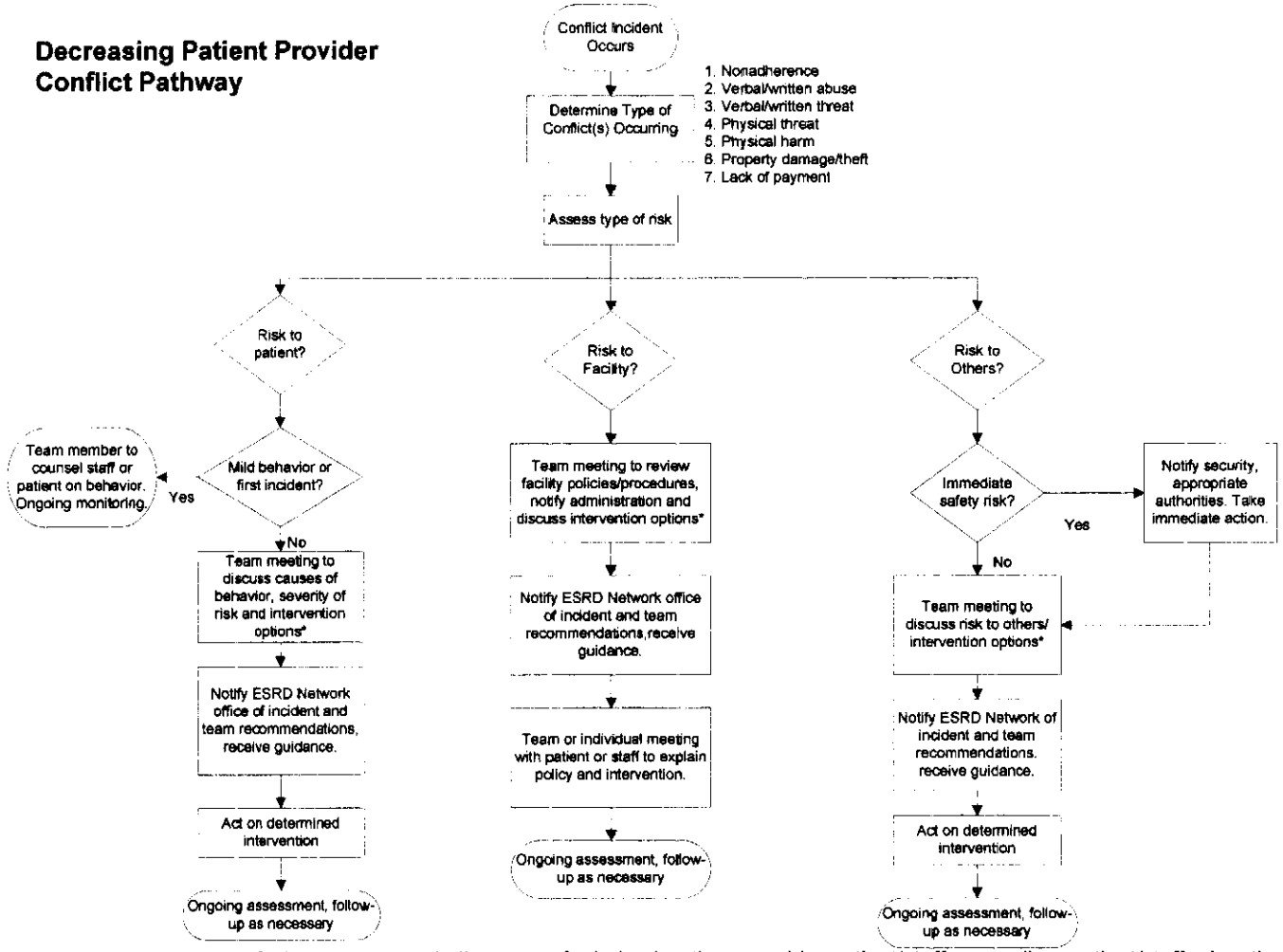
Wendy Funk Schrag

Wendy Funk Schrag, LMSW, ACSW
Renal Care Group
Patient Services Manager
625 Medical Center Drive
Newton, KS 67114
316-519-8018
wschrag@renalcaregroup.com

Condition	Comments
Physical environment §494.60	The new reg says that training should happen "periodically" for patients. It would be good to have this time frame clarified. Quarterly? Twice a year? Yearly? The new regs also talk about patient comfort in terms of temperature. I support this definition of patient comfort. In the past there has been no definition of what comfort means.
Patient rights §494.70	I propose that the regs use the algorithm currently in development by the CMS funded project Decreasing Patient Provider Conflict as a method for facilities to use for dealing with disruptive patients in making good faith attempts to deal with disruptive behavior (attachment).
494.80 Patient Assessment	A 20 day period to do a complete psychosocial assessment will be extremely difficult as it often takes several visits many social workers cover more than just one dialysis unit and are not there frequently. Because the new regs also suggst an additional visit to the assessment at the 3 month mark, I would suggest the initial psychosocial assessment be in two parts with part 1 being completed within 20 days and the full assessment completed within 3 months. The new regulation does not address annual updates to the initial assessment. CNSW and the ESRD Forum of Networks model for a medical record indicate an annual update to the initial psychosocial assessment should be part of the medical record. Can the new regs please define "reassessment"? Is this meant to be a care plan or an update of the initial assessment? I would suggest that it would be the first quarterly progress note entry. The new regs do not specify any time frame for regular progress note documentation by social workers and dietitians. CNSW supports quarterly progress notes by social workers.
Patient plan of care §494.90	I support deleting the transplant MD signature. The Development of the Plan of Care on page 92 of the regs does not specify a specific section for the social worker (emotional status). It has social services mentioned in rehabilitation, but rehabilitation should be a multidisciplinary effort. I would like to see a separate section for social work services asking if the patient is emotionally stable or unstable and what type of services are being provided to the patient in terms of emotional status or community resources. CNSW has a care plan template document which could be consulted for guidance.
Transplant referral tracking §494.90	Because the dialysis unit is not always kept informed by the transplant clinic of the process, I suggest the dialysis clinic complete an initial referral to the TX office but then the TX office be responsible for tracking the process via a form they could send to the dialysis clinic on a quarterly basis.
Care at home §494.100	Distance could be an issue with providing home visits "as appropriate." No definition of what "as appropriate" is and how or when to provide home visits to patients who live far away.
494.100 Care at home	Are RD and SW services provided by the Nursing Home or Skilled Nursing Facility? Do they need to meet the definitions for qualified personnel? Many nursing home social workers are BSWs which would not meet the qualified personnel requirements.
494.110	CMS is asking for guidance on tracking patient complaints/grievances. This is something that could be added to the facility monthly report to the Networks. Dialysis organizations should be given the opportunity to still use their own unique patient satisfaction survey even after CMS CAHPS survey is completed. The CAHPS is considering only sending the survey to a random sample of dialysis patients. In order for quality improvement to be done, LDO's typically give each and every patient the opportunity to complete a survey. The CAHPS survey also does not include peritoneal patients.
494.14 Personnel Qualifications	I support removing the grandfather clause for BSWs and making the MSW requirement stand stronger. BSWs could be used to assist the social worker in the areas outlined that identify MSWs should be taken out of (those duties in order to focus on more clinical outcomes). CNSW has a job description for a BSW that could be referenced. It supports using a BSW to assist an MSW with concrete resource tasks but not have their own specific caseload. (See attached).

Governance §494.180	If acuity-based staffing is adopted, this should also be addressed for social worker and dietitian ratios. CNSW currently has a suggested mathematical formula for social worker/patient staff ratios based on acuity which could be reviewed. In the regs where it discusses what states have mandated ratios, the Texas social work mandated ratios are not listed. If acuity-based ratios are adopted, then payment for dialysis treatments should also be adjusted for acuity in order for providers to be able to accommodate acuity-based staffing needs. (see attached CNSW social worker acuity based ratio guideline).

Decreasing Patient Provider Conflict Pathway



* Intervention options: Rule out any metabolic causes for behavior, then consider patient/staff counseling, patient/staff education, patient/family meetings including review of care plan, review of policies/procedures, ethics committee review, patient psychiatric evaluation referral and treatment, patient behavior contract, patient dismissal/discharge or staff suspension or termination only if all other interventions have failed or there is an immediate safety risk or harmful environment (no patient dismissal if the risk of the behavior does not affect others and is only a risk to the patient).

Social Services Resource Manager

GENERAL SUMMARY

Assist the Masters Social Worker (MSW) in providing resources for dialysis or transplant patients.

ESSENTIAL FUNCTIONS AND RESPONSIBILITES

1. Maintain a current list of all available community resources. Provide information to patients on how to contact needed resources.
2. Assist patients with indigent medication programs, educational information, and other needed resources.
3. Assist the MSW in collecting dialysis educational information for patients and families. Assist with organizational details of patient education classes.
4. Assist the MSW with collecting and entering quality of life survey data or other research projects.
5. Assist patients with questions they have about medical bills and explaining insurance coverage. Assist with charity applications as eligible.
6. Round on patients or visit with them as instructed by the MSW to determine unmet patient needs.
7. Assist with other tasks as requested by the MSW.

CRITICAL SKILLS AND ABILITIES

Capacity to form and maintain helping relationships with patients.
Sensitivity to racial and cultural diversity.
Able to set priorities under pressure.
Organization and time management.
Ability to assess needs and connect with resources.

WORK CONDITIONS

Desk, computer and phone required. Access to xerox, copy machine and email if available. Interactions with patients may occur in waiting area, treatment area or office.

MINIMUM EDUCATION AND EXPERIENCE

Bachelor's degree in social work or related human service field. Minimum requirement social service designee. Supervised by the MSW.

_____ _____

Employee's Signature Date

_____ _____

Supervisor's Signature Date

Council of Nephrology Social Workers

Position Statement on Social Work Staffing (1998)

End-Stage Renal Disease (ESRD) patients experience multiple losses and psychosocial risks associated with the diagnosis and treatment of ESRD and require comprehensive psychosocial services at various stages throughout the course of their illness and treatment. Potential barriers such as socioeconomic factors and other biopsychosocial risk factors, i.e. aging, comorbidity, and rural residence, can negatively impact patient treatment outcome. To ameliorate potential barriers to optimal treatment outcome and to promote maximum rehabilitation and the highest patient-perceived quality of life, ESRD patients must have appropriate access to masters-prepared nephrology social workers.

The following position statement prepared by the 1998 Executive Committee of the Council of Nephrology Social Workers is based on the "NKF/CNSW Approach to Patient/Social Worker Staffing" which is a research-based staffing guideline (see next article). The following statement uses the **minimal** psychosocial risk factors (PRF) and **minimal** social work functions for a hemodialysis outpatient setting. Most outpatient dialysis clinics would have a higher patient psychosocial risk profile than that calculated here. The formula can be used for transplant settings as well, but does not include information for peritoneal dialysis patients.

1997 United States Renal Data Systems (USRDS) data supports the percentages stated in the minimal psychosocial risk factors used to develop this position statement. Additionally, The Clinical Indicators for Social Work and Psychosocial Services in Nephrology Settings (NASW/NKF, 1994) supports the minimal social work staffing functions listed below. Having reviewed this data, the Council of Nephrology Social Workers supports the validity of the "NKF/CNSW Approach to Patient/Social Worker Staffing" which would indicate **one full-time MSW to every 75** patients using these minimal calculations.

Please review the entire "Approach" to develop a staffing ratio that reflects the specificity of a particular unit. Only **minimal** Psychosocial Risk Factors (PRF) were selected from the above mentioned guideline and used to develop this recommendation. For purposes of minimal social work staffing PRF would include:

BASE VALUE	0.30
>25% of patient population is socially disadvantaged or medicaid	+0.10
>25% of patient population is diabetic	+0.10
>25% of patient population is >60	+0.10
Total Facility Psychosocial Risk Factor	0.60

(other psychosocial risk factors usually found in the outpatient hemodialysis setting are excluded in this calculation to define "minimal" staffing needs)

The Case Function Ratio (CFR) has one of four values based on the number of social work functions performed. Six to nine (6-9) social work functions routinely performed is the **minimal** CFR allowed for in the "NKF/CNSW Approach to Patient Social Worker Staffing". According to this formula, a score of 45 represents 6-9 social work functions.

Minimal Social Work Case Functions, based on HCFA's Conditions of Coverage for Medicare Supplies of ESRD Services (1976) and National Association of Social Worker/National Kidney Foundation Clinical Indicators for Social Work and Psychosocial Services in Nephrology Settings (1994), used to develop this recommendation for purposes of **minimal** social work staffing include:

Psychosocial evaluations
Casework counseling (patients & families)
Groupwork
Facilitating community agency referral
Monitoring access and utilization of community agencies and services following referral
Team care planning and collaboration

(Many functions, which are not included in the above CFR, are generally accepted as routine social work functions in the outpatient hemodialysis setting. These include patient/family education, financial assistance, quality management and coordination of the renal rehabilitation program.)

Given these minimal values for Patient Risk Factor and Case Function Ratio, the following formula would be used:

$$\frac{\text{PRF} \times \text{Patient Population Served During Year}}{\text{Case Function Ratio}} = \text{Minimal Recommended Staffing Level}$$

$$\frac{0.6\ (\text{PRF}) \times 75\ \text{patients}}{45} = \frac{45}{45} = 1\ \text{MSW per 75 patients}$$

RECENT RESEARCH

Recent research shows that there is a statistically significant correlation between lower social worker caseload size and rehabilitation interventions offered (Callahan et al, 1998). This is also supported by a recent survey of the Life Options Rehabilitation Advisory Council's (LORAC) exemplary Practices Award Winners. The Exemplary Practices Award Winners are selected after review of facility rehabilitation programming for a designated period of time. This survey shows that 47% of ESRD facilities that received this award had an MSW to patient ratio of 75 to 1; 35% of ESRD facilities that received this award had an MSW to patient ratio of 76-90 (Schrag, 1998).

Recent studies also indicate a positive relationship between patient satisfaction and lower nephrology caseloads (Callahan et al, 1998), as well as patient's perceptions of the importance of access to nephrology social work services (Siegal et al, 1994; Rubin et al,, 997). Siegal's 1994 study of patient expectations related that greater than 84%of patients rely on clinical social workers to assist them with coping strategies, family adjustment, the impact of dialysis on their life and continuing to be involved with family activities. This same study showed that 91%of the patients believed that access to the nephrology social worker was important. Rubin's 1997 study showed that patients ranked the services provided by the nephrology social worker in the top four of twenty-five important aspects of care.

Summary

The National Kidney Foundation's Council of Nephrology Social Workers supports the validity of the "NKF/CNSW Approach to Patient/Social Worker Staffing" which would indicate one full-time MSW to every 75 patients using minimal calculations. Lower nephrology social worker caseloads increase the probability of positive rehabilitation outcomes and patient satisfaction with care.

References

Callahan, MB, Moncrief, M, Wittman, J, Maceda, M. "Nephrology social work intervention and the effect of
Caseload size on patient satisfaction and rehabilitation." Publication pending.

Council of Nephrology Social Workers. "NKF/CNSW Approach to Patient/Social Work Staffing." *Standards of Practice for Nephrology Social Work*. New York: National Kidney Foundation, 1995

Schrag WF, Witten B: Part I. Rehabilitation as an essential social work function: A study of LORAC exemplary practice winners. *Nephrol News Issues* 12(10):26-28,40, 1998.

Ruben,H, Jenckes, M, Fink, N, Meyer, K, Wu, A, Bass, E, Levin,N, & Powe, N. "Patient's view of dialysis care: Development of a taxonomy and rating of importance of different aspects of care." *American Journal of Kidney Disease*, 30 (6), 793-801

Siegal, B, Witten, B, Lundin, P. "Patient access and expectations of nephrology social workers." *Nephrology News & Issues* 8, 1994, 32+

United States Renal Data System. *1997 Annual Data Report*. National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Disease. Bethesda, MD, April 1997.

Reviewed EC 2001
Reviewed 2001

April 25, 2005

Center for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

This letter is being sent as a response to the proposed CMS Conditions of Coverage for Dialysis (CMS-3818-P). As a Renal Social Worker for the past 14 years, I feel that I am well-qualified to submit a response to some of the proposed changes in the CMS regulations. Please note that I have outlined my responses to particular issues by using the specific issue identifier numbers that I extracted from this proposal.

494.80(b)(1) and (2): Patient Assessment and Re-assessment of New Patients-

While I support the stronger emphasis being placed on a comprehensive interdisciplinary approach to patient assessment, I strongly believe that 20 days is not an appropriate length of time for obtaining a complete and accurate patient assessment. Many patients start dialysis in both a physically and mentally compromised status and they are not able to adequately participate in this type of interview or evaluation process. So, in essence, the team would end up with a flawed basis for developing a care plan for a patient. I do not see the value of an assessment of this nature being completed so early in their initiation of treatment. I would propose instead that a brief informal initial assessment be conducted within 2-4 weeks of admission and that a comprehensive formal team assessment be completed within 60-90 days of admission. In the end, I strongly believe that the patient will benefit more from the outcome of an assessment completed at this time. With regards to the "comprehensive reassessment for new patients within 3 months of completion of the initial comprehensive assessment", I recommend that this requirement be eliminated. With more time, as I proposed (60-90 days), to develop the initial assessment, the need for the reassessment at 3 months would naturally be eliminated. As would the

care plan requirement at 30 days as proposed. It might be more useful to require that all new ESRD patients be considered "unstable", for care planning purposes, for the first 4-6 months of being on dialysis. And emphasis should be placed on rehabilitation, adjustment, and compliance education/interventions within the care planning process for those first 6 months. From my practical experience with dialysis patients, it would also be more useful to develop an initial comprehensive care plan at 60 or 90 days. This would not eliminate the responsibility of the team to address the patient's immediate needs upon admission and for those first 60 to 90 days. The Social Worker should still be required to have contact with a new patient within 7 days of admission and to screen for and intervene with all immediate psychosocial needs (practical, emotional, and educational).

494.80(1)- In the section that proposes that the facility must perform a comprehensive reassessment at least annually, I feel that the wording of the proposal is unclear and confusing. It is difficult to discern what type of "comprehensive reassessment" is being required. A "comprehensive patient care plan" is not necessarily equivalent to a "comprehensive reassessment" of a patient. It may just be a matter of semantics, but I believe that if this section remains in the proposal that it will cause a great deal of confusion as it is worded.

494.90:Patient Plan of Care-

I support the elimination of the separate requirement for a patient long-term care program. While its initial intent was admirable, I feel that with greater and more frequent attention being placed on rehabilitation and transplantation monitoring, that there is no need for this program any longer.

I also support the elimination of the transplant surgeon/designee, facility medical director, and the home dialysis physician from the "interdisciplinary" team for the purposes of developing the long term program.

494.90 (a)(6): Rehabilitation Status-

I strongly support the emphasis on renal rehabilitation within the proposed changes. Without stricter guidelines and requirements in this area, renal rehabilitation will not get the time and attention that it deserves from the renal team. The language in this section, however, needs to be much more directive and specific if it is to accomplish this goal. The renal team must view rehabilitation as a required and important responsibility. I encourage more detailed direction in this section. It might be useful to require that a "comprehensive interdisciplinary rehabilitation assessment" be required on every patient. This type of assessment could be done separately but along with the initial comprehensive assessment and could be required to be reviewed every 3 or 6 months. This would send a clear message about the importance of rehabilitation to the patient's care!

494.90(g):Social Services-

I believe that it is critical that the wording in this section be stronger and more directive. As the history of renal care has shown, dialysis clinic administrators (and the corporations that guide them) do not often understand or support the clinical role of the Social Worker. Consequently, a Social Worker is often assigned to many clinical tasks that consume a lot of his or her time. This, in turn, prevents or limits the amount of time that can be devoted to the important emotional, education, and psychological needs of patients that only the Social Work can address. Assigning non-clinical tasks (such as admissions, travel, and insurance) would be critical to freeing up the Social Worker for these other purposes.

494.140(d): Personnel Qualification-Social Worker-

I support the proposal to remove the grandfather clause from the requirements as stated.

I also support the proposal to require a Master's level Social Worker (MSW) to perform the Social Worker role in the dialysis setting. MSW's are educated and qualified to provide counseling and therapy to dialysis patients. It is important, however, to realize that

MSW's do require the supervision of an LCSW if they are not licensed for clinical practice. LCSW supervision should, therefore, be required as well. In addition, as I stated earlier, it is critical that non-clinical tasks be directed away from the Social Worker so that he or she can perform adequately in this area. It would also be important to address patient-to-staff ratios for Social Workers. This was not outlined in the proposed regulations and this is a important area as well. If Social Workers were not acting as admission clerks and travel coordinators, and the money was more wisely spent on using the skills of the Social Worker as they were intended, the patients would greatly benefit and it would, in the end, positively affect the cost of patient care.

Issue Identifier	Linda Clapper, LMSW's Comments on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P
LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/05-1622.pdf
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add:*** A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained *patient* and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:*** Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add:*** "Facilities must accommodate mobility, hearing, vision, or other disabilities or language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***References:*** ADA
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. ***Rationale***: HIPAA privacy ***Reference:*** *Protecting the Privacy of Patients' Health Information* ***Comment***: CNSW Supports the inclusion of the proposed (c) (2) regarding facility temperature. ***Rationale***: A common complaint from dialysis patients is in regards to the facility climate. A patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who are not comfortable.
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Add***: (2) Require facility to ask the patient to *demonstrate understanding* of information provided. ***Rationale***: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. ***References:*** Johnstone, 2004; Juhnke & Curtin, 2000; Kaveh & Kimmel, 2001 ***Comment & Addition to a6:*** CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment. ***Rationale:*** We propose to require that a facility inform patients about all available treatment modalities

	and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible. For patients to truly have choices in their modalities, they must not only know what types of treatment exist, but where they can be obtained. Home Dialysis Central (www.homedialysis.org) has a searchable database of clinics that offer any type of home dialysis and US maps for each home modality showing a 120 mile radius from clinic locations. ***Comment:*** CNSW supports the language of a5 ***Rationale:*** Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. ***Add***: (new 17) "Have access to a qualified social worker and dietitian as needed" ***Rationale:*** Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed. ***References:*** Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht, 2004a ***Add***: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis" ***Rationale:*** New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial. ***References:*** Curtin et al,1996; Rasgon et al, 1993, 1996 ***Add***: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school" ***Rationale:*** Same as above for new 18. ***References:*** Same as above for new 18, plus:Mayo 1999 ***Add***: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed" ***Rationale:*** These interventions have been shown to improve patient rehabilitation outcomes. ***References:*** Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999. ***Add***: (new 21) "Attend care planning meetings with or without representation."

	Rationale: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings. ***Add***: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists." ***Rationale:*** Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year. ***Add***: (new 23) "Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation." ***Rationale:*** Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate. ***Add***: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate." ***Rationale:*** Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate. ***Add***: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them" ***Rationale***: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them. ***Reference:*** McLaughlin et al., 2003 ***Add***: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility." ***Rationale***: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal

	patient functioning and adjustment ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	***Add to b1***: "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others" ***Rationale***: Facilities should be encouraged first to try counseling to resolve difficult situations ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Add***: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." ***Rationale:*** The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis. ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Change***: (renumbered 3) Delete or define "reducing...ongoing care." ***Rationale:*** This phrase is unclear.
494.70 Condition Patients' Rights (c) Standard: Posting of rights.	***Add***: "Facilities with patients who cannot read the patients' rights poster must provide an alternate method to inform these patients of their rights which can be verified at survey." ***Rationale & References***: Americans with Disabilities Act, Civil Rights Act
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Add***: (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation."

	Rationale: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions. ***References;*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Comment:*** CNSW supports the language of a2, a3, a4, a5, a6 ***Change***: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)." ***Rationale***: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response. ***Comment:*** CNSW supports the language of a8 ***Add***: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)." ***Rationale***: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality. ***References:*** Curtin, Bultman, Schatell & Chewning, 2004; Curtin & Mapes, 2001 ***Add***: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate

	basis for non-referral." ***Rationale:*** Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. ***Comment:*** CNSW supports the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. ***Comment:*** CNSW supports the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess ***Add***: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low PCS scores predict higher morbidity and mortality in research among ESRD patients. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." ***Rationale:*** Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vii) "Depression per patient report, staff observation or validated depression screening survey" ***Rationale:*** Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death. ***References;*** Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein & Finklestein, 2005 ***Add***: (new viii) "Loss of or threatened loss of employment per patient report"

	Rationale: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. ***References;*** Blake, Codd, Cassidy & O'Meara, 2000; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004; Witten, Schatell & Becker, 2004
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process ***Add***: (new 3) "*Psychosocial status*. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. ***Add***: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance with § 494.80(a)(9)(ii) of this part. ***Rationale***: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken

	in the area of home dialysis. ***Add***: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning), (ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form (iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status. (iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline." ***Rationale***: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed." ***Rationale***: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking	***Comment:*** CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at

	least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. ***References;*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell & Chewning, 2004; Johnstone, et al., 2004
494.100 Condition Care at home.	***Comment:*** CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients. **Rationale**: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility. ***Add***: (new 3iv) "Implementation of a social work care plan" ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.
494.100 Condition Care at home. (c) Standard: Support services.	***Add to 1i***: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care." ***Rationale***: Members of the interdisciplinary team can offer better care to patients after seeing the patient

	in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?) ***Add to 1iv***: "Patient consultation with all members of the interdisciplinary team, as needed." ***Rationale***: The language of this part of the proposed conditions is vague and subject to varying interpretation
NEWCONDITION Staff assisted skilled nursing home dialysis	***Add:*** A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:***Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of the proposed conditions of coverage.
§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.	***Add***: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors." ***Rationale:*** To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved. ***Add***: (2)(new iii) "Psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle

	changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality. ***Add***: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form" ***Rationale:*** These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes. ***Comment:*** CNSW agrees that dialysis providers must measure patient satisfaction and grievances. CNSW supports the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.
494.140 Condition Personnel qualifications	***Comment:*** CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section. ***Rationale & References***: It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully

	with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommend that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination of benefit periods. • 44% of social workers were primarily responsible for completing patient admission paperwork. • 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship). • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).
494.140 Condition Personnel qualifications (d) Standard: Social	***Change the language of d to***: *Social worker*. The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the

worker.	licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks. ***Rationale & References***: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition. Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge

of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction

	adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
494.140 Condition Personnel qualifications	***Add***: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage. ***Rationale & References***: We agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his

	survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that: • 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training. • 61% of social workers were solely responsible for arranging patient transportation. • 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time. • 26% of social workers were responsible for initial insurance verification. • 43% of social workers tracked Medicare coordination periods. • 44% of social workers were primarily responsible for completing admission packets. • 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust. • Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs. This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
§**494.180 Condition** Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis

providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing).

Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients.

In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59).

Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios):

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000)

	discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression. Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
§494.180 Condition Governance. (b4) Standard. Adequate number of qualified and trained staff.	***Comment:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§494.180 Condition Governance. (b5) Standard. Adequate number of qualified and trained staff.	***Add (5ix):*** Add "Psychosocial issues related to ESRD and its treatment regimes, as provided by the facility social worker." ***Comment:*** Technicians have the most contact with patients and need to be attuned to patients' psychosocial issues so as to most effectively collaborate with the social worker and achieve patient outcomes.
§494.180 Condition Governance. (h) Standard: Furnishing data and information for ESRD program administration.	(h) Standard: Furnishing data and information for ESRD program administration. ***Add***: (3)(new iv) "Annual reporting of facility aggregate functioning and well-being (physical component summary scores and mental component summary scores) and vocational rehabilitation status according to categories on the CMS 2728 form." ***Rationale***: These data would be easy to collect, would permit comparisons between clinics, and would serve as a basis for QAPI.

(Linda Clapper, LCSW)
Norcross Dialysis Center
4650 Jimmy Carter Blvd, Suite 111-113
Norcross, GA 30093

REFERENCES

ADA, Title III, Part 36, Subpart A, Section 36.303, auxiliary aids (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-97857)

ADA Title III, Part 36, Subpart A, Section 36.304, removal of barriers (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-91481)

Anderson, R. (1986). The CSWE Accrediting Standards for Social Work Education. *Social Work in Education*. CCC Code: 0162-7961/86.

Andreucci, V. E., et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) data on medications in hemodialysis patients. *Am J Kidney Dis.* 44(5 Suppl 3):61-7, 2004.

Auslander, G. K., Buchs, A. (2002). Evaluating an activity intervention with hemodialysis patients in Israel. Social Work Health Care. 35(1-2):407-23.

Auslander, G., Dobrof, J., & Epstein, I. (2001). Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. *Social Work in Health Care*, 33(3/4), 129-151.

Beder, J. (1999). Evaluation research on the effectiveness of social work intervention on dialysis patients: the first three months. *Social Work in Health Care*, 30(1), 15-30.

Beder, J., Mason, S., Johnstone, S., Callahan, M. B., & LeSage, L. (2003). Effectiveness of a social work psychoeductional program in improving adherence behavior associated with risk of CVD in ESRD patients. *Journal of Nephrology Social Work*, 22, 12-22.

Blake C, Codd MB, Cassidy A, O'Meara YM. Physical function, employment and quality of life in end-stage renal disease. *J Nephrol.* 13(2):142-9, 2000.

Bogatz, S., Colasanto, R., & Sweeney, L. (2005). Defining the impact of high patient/staff ratios on dialysis social workers. *Nephrology News & Issues*, Jan, 55-60.

Bonner, C., Dean, R., & Greenspan, R. (1989) Standards for Practice: The Development of the Clinical Social Worker in the First Two Years. *The Clinical Supervisor* 1989. 7(4), 31-45.

Booz, A., & Hamilton, Inc. (1987) *The Maryland Social Work Services Job Analysis and Personnel Qualifications Study*. Prepared for the Department of Human Resources State of Maryland

Burrows-Hudson, S. (1995). Mortality, morbidity, adequacy of treatment, and quality of life. *ANNA Journal*, 22(2), 113-121.

Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M. (1998). Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. *Journal of Nephrology Social Work*, 18, 66-79.

Callahan, M. B., Witten, B., & Johnstone, S. (1997). Improving quality of care and social work outcomes in dialysis. *Nephrology News & Issues*, 2(4), 42-43.

Chang, C. F., Winsett, R. P., Gaber, A. O., & Hathaway, D. K. (2004) Cost-effectiveness of post-transplantation quality of life intervention among kidney recipients, *Clinical Transplantation*, 18(4), 407-415.

Coulton, C. (1979). A study of the person-environment fit among the chronically ill. *Social Work in Health Care*, 5(1), 5-17.

Council on Social Work Education: Commission on Accreditation, *Handbook of Accreditation Standards and Procedures* (Fourth Edition). Subsection B5.7.9 and M5.7.11 and Subsection B5.7.7 and M5.7.8, pp. 99, 137.

Curtin RB, Oberley ET, Sacksteder P, Friedman A. (1996). Differences between employed and nonemployed dialysis patients. *Am J Kidney Dis*. 27(4):533-40.

Curtin RB, Mapes DL. (2001) Health care management strategies of long-term dialysis survivors.*Neph Nurs J.* 28(4):385-394.

Curtin RB, Bultman DC, Schatell D, Chewning BA. (2004) Self-management, knowledge, andfunctioning and well-being of patients on hemodialysis. *Neph Nurs J* 31(4):378-387.

Curtin RB, Bultman DC, Thomas-Hawkins C, Walters BA, Schatell D. Hemodialysis patients' symptom experiences: effects on physical and mental functioning. *Nephrol Nurs J.*;29(6):562, 567-74; discussion 575, 598, 2002.

Curtin RB, Klag MJ, Bultman DC, Schatell D. Renal rehabilitation and improved patient outcomes in Texas dialysis facilities. Am J Kidney Dis.;40(2):331-8, 2002.

Curtin RB, Sitter DC, Schatell D, Chewning BA. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Nephrol Nurs J* 31(4):378-86, 396; quiz 387, 2004.

DeOreo, P. B. (1997). Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *American Journal of Kidney Diseases*. 30(2), 204-212.

Devins, G. M., Mandin, H., Hons, R. B., Burgess, E. D., Klassen, J., Taub, K., Schorr, S., Letourneau, P. K., & Buckle, S. (1990), Illness intrusiveness and quality of life in end-stage renal disease: comparison and stability across treatment modalities. *Health Psychology*, 9(2), 117-142.

Dhooper, S., Royse, D., & Wolfe, L. (1990) Does social work education make a difference? *Social Work Education,* 1990, 35 (1), 57-61.

Dobrof, J., Dolinko, A., Lichtiger, E., Uribarri, J., & Epstein, I. (2001) Dialysis patient characteristics and outcomes: the complexity of social work practice with end-stage renal; disease population. *Social Work in Health Care*, 33, 105-128.

Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf)

Frank, A., Auslander, G. K., & Weissgarten, J. (2003). Quality of life of patients with end-stage renal disease at various stages of the illness. *Social Work in Health Care*, 38(2), 1-27.

Gudes, C. M. (1995). Health-related quality of life in end-stage renal failure. *Quality of Life* ESRD Network of Texas (2002). Social Services Practice Recommendations. *http://www.esrdnetwork.org/professional_standards.htm*

Holley, J. L., Barrington, K., Kohn, J., & Hayes, I. (1991). Patient factors and the influence of nephrologists, social workers, and nurses on patient decisions to choose continuous peritoneal dialysis. *Advances in Peritoneal Dialysis*, 7, 108-110.

Johnstone, S. (2003). Evaluating the impact of a physical rehabilitation program for dialysis patients. *Journal of Nephrology Social Work*, 22, 28-30.

Johnstone, S. & Halshaw, D. (2003) Making peace with fluid social workers lead cognitive-behavioral intervention to reduce health-risk behavior. *Nephrology News & Issues* (12), 20-31.

Johnstone, S., Seamon, V. J., Halshaw, D., Molinair, J., & Longknife, K. (1997). The use of medication to manage patient-staff conflict in the dialysis clinic. *Advances in Renal Replacement Therapy*, 4(4), 359-371.

Johnstone, S., Walrath, L., Wohlwend, V., & Thompson, C. (2004). Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. *Advances in Chronic Kidney Disease*, 11(2), 210-216.

Juhnke, J & Curtin, R.B. (2000) New study identifies ESRD patient education needs. *Nephrology News & Issues*14(6):38-9.

Kalantar-Zadeh, K., Kopple, J. D., Block, G., & Humphreys, M. H. (2001). Association among SF36 quality-of-life measures and nutrition, hospitalization, and mortality in hemodialysis. *Journal of the American Society of Nephrology*, 12, 2797-2806.

Kaitelidou, D., Maniadakis, N., Liaropouls, L., Ziroyanis, P., Theodorou, M., & Siskou, O. (2005). Implications of hemodialysis treatment on employment patterns and everyday life of patients. *Dialysis & Transplantation*, 34(3), 138-147, 185.

Katon, W., & Schulberg, H. (1997). Epidemiology of depression in primary care. *General Hospital Psychiatry,*14, 237-247.

Kaveh K & Kimmel PL. (2001). Compliance in hemodialysis patients: multidimensional measures in search of a gold standard. *American Journal of Kidney Diseases* 37(2):244-66.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D., Verne, D., Alleyne, S., & Cruz, I. Veis, J (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International*, 5(10), 2093-2098.

Kimmel, P., Peterson, R., Weihs, K., Simmens, Alleyne, S., Cruz, I., & Veis, J (1998). Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. *Kidney International*, 54, 245-254.

Kimmel PL et al Survival in hemodialysis patients: the role of depression. *J Am Soc Nephrol*. 4(1):12-27, 1993.

King K, Moss AH. The frequency and significance of the "difficult" patient: The nephrology community's perceptions. *Adv Chronic Kidney Dis*. 2004 Apr;11(2):234-9.

Knight EL et al. The association between mental health, physical function, and hemodialysis mortality. *Kidney Int*. 63(5):1843-51 2003.

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 41(11):1284-92, 2003.

Kutner NL et al. Functional impairment, depression, and life satisfaction among older hemodialysis patients and age-matched controls: a prospective study. *Arch Phys Med Rehabil*. 81(4):453-9, 2000.

Levenson, J., & Olbrisch, M. (2000). Psychosocial screening and candidate selection. In P. Trzepacz & A. DiMartini (Eds.), *The transplant patient: biological, psychiatric, and ethical issues in organ transplantation* (pp. 21-41). Cambridge: Cambridge University Press.

Lowrie EG, Curtin RB, LePain N, Schatell D. Medical outcomes study short form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. *Am J Kidney Dis*. 41(6):1286-92, 2003.

Mapes, D., Bragg-Gresham, J. L. Bommer, J. Fukuhara, S., McKevitt, P., & Wikstrom, B (2004). Health-related quality of life in the dialysis outcomes and practice patterns Study (DOPPS) American Journal of Kidney Diseases, 44 suppl(5), 54-60.

Mayo K. (1999)Can evening dialysis services improve the chances of rehabilitation? A Network #7 study. *Nephrol News Issues*. 13(6):37-8.

McKinley, M., & Callahan, M.B. (1998). Utilizing the case management skills of the nephrology social worker in a managed care environment. In National Kidney

Foundation (Ed.), *Standards of practice for nephrology social work, 4th ed*, (pp. 120-128). NY: National Kidney Foundation.

McLaughlin K, Manns B, Mortis G, Hons R, Taub K. (2003). Why patients with ESRD do not select self-care dialysis as a treatment option. *Am J Kidney Dis*. 41(2):380-5.

Merighi, J. R., & Ehlebracht, K. (2005). Emotional Exhaustion and Workload Demands in Renal Social Work Practice, *Journal of Nephrology Social Work*, 24, 14-20, *Journal of Nephrology Social Work*, in press

Merighi, J. R., & Ehlebracht, K. (2004a). Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. *Nephrology News & Issues*, 18(4), 58-63.

Merighi, J. R., & Ehlebracht, K. (2004b). Issues for renal social workers in dialysis clinics in the United States. *Nephrology News & Issues*, 18(5), 67-73.

Merighi, J. R., & Ehlebracht, K. (2004c). Unit-based patient services and supportive counseling. *Nephrology News & Issues*, 18(6), 55-60.

Morrow-Howell, N. (1992). Clinical case management: the hallmark of gerontological social work. *Geriatric Social Work Education*, 18, 119-131.

National Association of Social Workers (1981) *Standards for the classification of social work practice*. Maryland: National Association of Social Workers.

Promoting Excellence in End-of-Life Care (2002), *End-Stage Renal Disease Workgroup Recommendations to the Field,* Missoula, MT: The Robert Wood Johnson *Protecting the Privacy of Patients' Health Information* (http://www.hhs.gov/news/facts/privacy.html)

Rasgon SA, Chemleski BL, Ho S, Widrow L, Yeoh HH, Schwankovsky L, Idroos M, Reddy CR, Agudelo-Dee L, James-Rogers A, Butts E. (1996). Benefits of a multidisciplinary predialysis program in maintaining employment among patients on home dialysis. *Adv Perit Dial*. 12:132-5.

Rabin, P. L. (1983). Psychiatric aspects of end-stage renal disease: diagnosis and management. In W. J. Stone & P. L. Rabin (Eds.) *End-Stage renal disease: an integrated approach, (*pp. 111-147). NY: Academic Press.

Rasgon, S., Schwankovsky, L., James-Rogers, A., Widrow, L., Glick, J., & Butts, E. (1993). An intervention for employment maintainence among blue-collar workers with end-stage renal disease. *American Journal of Kidney Diseases*, 22(3), 403-412.

Rau-Foster M. The dialysis facility's rights, responsibilities, and duties when there is conflict with family members. *Nephrol News Issues*. 15(5):12-4, 2001.

Renal Physicians Association and American Society of Nephrology. *Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis*

Rosen, L. S. (1999). Common psychosocial factors in the treatment of end stage renal disease. *Journal of Nephrology Social Work*, 19, 69-72.

Russo, R. (2002). The role of the renal social worker in the 21st century. *Nephrology News & Issues*, 16(3), 38,40.

Rubin, H., Jenckes, M., Fink, N., Meyer, K., Wu, A., Bass, E., Levin, N., & Powe, N. (1997). Patient's view of dialysis care: development of a taxonomy and rating of importance of different aspects of care. *American Journal of Kidney Disease*, 30(6), 793-801.

Siegal, B., Witten, B., Lundin, A.P (1994). Patient access and expectations of nephrology social workers. *Nephrology News and Issues*, April, 32-33,40.

Sikon, G. M. (2000). Pre-dialysis education reduces anxiety in the newly diagnosed chronic renal failure patient. *Dialysis & Transplantation*, 6, 346, 344-345.

Tong E. M. & Nissenson, A. R. (2002). Dialysis in nursing homes. *Seminars in Dialysis*. 15(2):103-6.

Vourlekis, B., & Rivera-Mizzoni, R. (1997). Psychosocial problem assessment and ESRD patient outcomes. *Advanmces in Renal Replacement Therapy*, 4(2), 136-144.

Wallace, S., Goldberg, R., & Slaby, A. (1984). *Guide for clinical social work in health care*. NY: Praeger Publishers.Witten B, Howell P, Latos D. (1999). Improving employment outcomes: the renal care team's role. *Nephrol News Issues*. 13(3):46-8.

Witten B, Schatell DR, Becker BN. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) *J Am Soc Nephrol*. 2004; 15:633A.

Wuerth D, Finklestein SH, Finklestein FO. The identification and treatment of depression in patients maintained on dialysis. *Semin Dial*. 18(2):142-6, 2005.

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May 3, 2005

Department for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern:

I am writing in response to the proposed Conditions for Coverage for End-Stage Renal Disease Facilities. I have worked as a renal social worker for the past fifteen years and I am a member of the National Kidney Foundation Council of Nephrology Social Workers. The executive board, along with input from dialysis social workers from various parts of the country, has outlined the attached comments. I have carefully reviewed these and strongly support the recommendations as presented.

I feel the following areas are of most importance:

494.140 Condition: Personnel qualifications
Recommend this section outline clearly the responsibilities of each team member. Social workers should be responsible for the clinical tasks of assessment , counseling, education. I support the statements in the preamble to the proposed changes that identifies services such as Medicare/Medicaid eligibility, transportation, housing, medications as important but services that can be performed for the patient by other staff to allow the MSW to provide needed social work services of counseling, psychosocial evaluation, rehabilitation, mediating conflicts, and education.

494.180 Condition: Governance
A specific social worker-patient ratio needs to be included in the condition of coverage. CNSW recommend ratio of 75:1 which is ideal. Most social workers have a much larger caseload currently and are responsible for nonprofessional services and unit tasks. Without a specific ratio, social workers will not be able to provide the mandated social work services to all patients.

494.80 Condition: Patient Assessment Standardized tools should be used in patient assessment and reassessment. I support the addition of reassessment after three months on dialysis.

I have attached the CNSW Comment on the changes. Thank you for taking the time to review these comments and for your consideration.

Sincerely,

Laurie McGaffigan, MSW LCSW
111 White Oak Drive
Wheaton, Illinois 60187

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 1
LOCATION OF COC	PROPOSED DIALYSIS COC that are identified in this document can be found at: http://a257.g.akamaitech.net/7/257/2422/09feb20050800/edocket.access.gpo.gov/2005/pdf/05-1622.pdf
494.10 Definitions Dialysis facility *NEW* Staff assisted skilled nursing home dialysis	***Add***: A new category for dialysis provided in a nursing home setting ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained *patient* and/or a helper. Making these treatments equivalent ignores the important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. ***Reference:*** Tong & Nissenson, 2002
494.20. Condition Compliance with Federal, State, and local laws and regulations	***Add***: "Facilities must accommodate mobility, hearing, vision, or other disabilities or language and communication barriers" ***Rationale***: Healthcare settings are covered entities under the Americans with Disabilities Act. ***References:*** ADA
494.60 Condition Physical Environment. (c) Patient care environment	***Add to c1***: Require facilities to be accessible to people with disabilities. ***Rationale***: Americans with Disabilities Act ***Reference:*** ADA ***Add to c1***: Require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. ***Rationale***: HIPAA privacy ***Reference:*** *Protecting the Privacy of Patients' Health Information* ***Comment***: CNSW Supports the inclusion of the proposed (c) (2) regarding facility temperature. ***Rationale***: A common complaint from dialysis patients is in regards to the facility climate. A patient-centered care approach dictates that facilities need to have a plan in place to accommodate patients' preferences for climate, and address the concerns of patients who are not comfortable.
494.70 Condition Patients' Rights (a) Standard: Patients' rights	***Add***: (2) Require facility to ask the patient to *demonstrate understanding* of information provided. ***Rationale***: Without this requirement, it would be very easy for staff to believe that they had informed a patient without realizing that, in fact, the patient did not understand the information. ***References:*** Johnstone, 2004; Juhnke & Curtin, 2000; Kaveh & Kimmel, 2001 ***Comment & Addition to a6:*** CNSW supports the language of a6 with the recommended addition of requiring facilities to inform patients of all available treatments (in-center hemodialysis, CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, nocturnal home hemodialysis, transplant), and to provide a list of facilities where treatments are offered within 120 miles if the facility does not offer that treatment. ***Rationale:*** We propose to require that a facility inform patients about all available treatment modalities

and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible. For patients to truly have choices in their modalities, they must not only know what types of treatment exist, but where they can be obtained. Home Dialysis Central (www.homedialysis.org) has a searchable database of clinics that offer any type of home dialysis and US maps for each home modality showing a 120 mile radius from clinic locations.

Comment: CNSW supports the language of a5
Rationale: Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions.

Add: (new 17) "Have access to a qualified social worker and dietitian as needed"
Rationale: Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.
References: Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi & Ehlebracht, 2004a

Add: (new 18) "Be informed that full- or part-time employment and/or schooling is possible on dialysis"
Rationale: New patients do not know what to expect from dialysis and may be told that they must go on disability, when paid employment (with insurance) or schooling may be possible for them, particularly if they have access to evening shifts, transplant or home dialysis therapies. The purpose of dialysis is to permit the highest possible level of functioning despite kidney failure, thus this element of rehabilitation is crucial.
References: Curtin et al,1996; Rasgon et al, 1993, 1996

Add: (new 19) "Have a work-friendly modality (PD or home hemodialysis) or schedule that accommodates work or school"
Rationale: Same as above for new 18.
References: Same as above for new 18, plus: Mayo 1999

Add: (new 20) "Receive referral for physical or occupational therapy, and/or vocational rehabilitation as needed"
Rationale: These interventions have been shown to improve patient rehabilitation outcomes.
References: Beder, 1999; Dobrof et al., 2001; Witten, Howell & Latos, 1999.

Add: (new 21) "Attend care planning meetings with or without representation."
Rationale: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings.

Add: (new 22) "Request an interdisciplinary conference with the care team, medical director and/or nephrologists."
Rationale: Patients don't realize that they can convene a care conference, and this is one way to obtain feedback from the team outside of the normal care planning meeting, which might only be done once/year.

Add: (new 23) "Refuse cannulation by a nurse or technician if access problems occurred with that staff member in the past until evidence of retraining is provided. Patients may also request another staff person to observe cannulation."
Rationale: Patients have only a limited number of potential vascular access sites, and if a staff person was responsible for causing access damage or hospitalization in the past, patients must have the right to protect themselves by refusing care from that staff person. Despite the obvious interpersonal and convenience issues this will cause for facilities, this is a patient safety issue that also has the potential to reduce cost to the system of hospitalization from vascular access problems. This will also encourage clinics to help their staff improve their cannulation skills and teach patients to self-cannulate.

Add: (new 24) "Be informed that self-cannulation is possible and be offered training to self cannulate."
Rationale: Having a single, consistent cannulator can help preserve vascular accesses and reduce hospitalizations. Since the patient is always present for the hemodialysis treatment, he or she should be encouraged whenever possible to become his/her own cannulator. Clinics should not be allowed to have a policy denying a willing patient the right to learn to self-cannulate.

Add: (new 25) "Be informed of topical analgesics for needle pain and how to obtain them"
Rationale: Needle fear and needle pain are largely unaddressed issues in hemodialysis, despite the large (14-15 gauge) needles that must be used at each treatment. Patients should be able to undergo a painless treatment, and low-cost, over-the-counter, 4% lidocaine preparations are available that will not harm the access and will provide pain relief. Patients should be told that these products exist and where to obtain them.
Reference: McLaughlin et al., 2003

Add: (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."

summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or referring the patient to further mental health evaluation."
Rationale: The preamble to the *Conditions for Coverage* discussed the importance of measuring functioning and well-being—but stated that there was "no consensus" about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions.
References: □DeOreo, 1997; □Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; □Knight et al. 2003; □Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; □Mapes et al., 2004

Comment: CNSW supports the language of a2, a3, a4, a5, a6

Change: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)."
Rationale: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.

Comment: CNSW supports the language of a8

Add: (a9)(new i) "The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for nonparticipation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)."
Rationale: Life Options research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.

	References: Curtin, Bultman, Schatell & Chewning, 2004; Curtin & Mapes, 2001 ***Add***: (9)(new ii) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral." ***Rationale***: Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. ***Comment:*** CNSW supports the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard. Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: We recommend combining an initial team assessment and care plan as they work in concert: a care plan should address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. ***Comment:*** CNSW supports the language of b2
494.80 Condition Patient assessment (d) Standard: Patient reassessment	***Change***: (d2iii) to "significant change in psychosocial needs as identified in 494.80 a7." ***Rationale***: Referring back to the specific psychosocial issues recommended to be added to 494.80 a7 will eliminate any ambiguity of needs to reassess ***Add***: (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being." ***Rationale***: Low PCS scores predict higher morbidity and mortality in research among ESRD patients. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being." ***Rationale***: Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments. ***References:*** DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer & Williams, 2003; Lowrie, Curtin, LePain & Schatell, 2003; Mapes et al., 2004 ***Add***: (new vii) "Depression per patient report, staff observation or validated depression screening survey" ***Rationale***: Multiple studies report a high prevalence of untreated depression in dialysis patients;

	depression is an independent predictor of death. ***References:*** □Andreucci et al., 2004.; □Kimmel, 1993; □Kimmel, 1998; □Kutner et al., 2000.; □Wuerth, Finklestein & Finklestein, 2005 ***Add***: (new viii) "Loss of or threatened loss of employment per patient report" ***Rationale***: Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes. ***References:*** □Blake, Codd, Cassidy & O'Meara, 2000; □Lowrie, Curtin, LePain & Schatell, 2003; □Mapes et al., 2004; □Witten, Schatell & Becker, 2004
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient or his or her representative must initial the reason provided, and sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process ***Add***: (new 3) "*Psychosocial status.* The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. ***Add***: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance

	with § 494.80(a)(9)(ii) of this part. ***Rationale***: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis. ***Add***: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning), (ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form (iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status. (iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline." ***Rationale***: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed." ***Rationale***: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (c) Standard: Transplantation referral tracking	***Comment:*** CNSW supports the language of (c) and recommends its inclusion in the final conditions. In addition, we would also like to see language which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant.

Issue Identifier	CNSW Comment on Conditions for Coverage for End Stage Renal Disease Facilities File code CMS–3818–P pg 9
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies (xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. ***References:*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell & Chewning, 2004; Johnstone, et al., 2004
494.100 Condition Care at home.	***Comment:*** CNSW agrees that services to home patients should be at least equivalent to those provided to in-center patients. **Rationale**: Home dialysis patients are patients of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected outcomes as any other patient of the facility. ***Add***: (new 3iv) "Implementation of a social work care plan" ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that

	psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, a social work care plan is as equally important as other aspects of training for home patients. It is important to specify a "social work care plan" to ensure that it is conducted by a qualified social worker as identified below.
494.100 Condition Care at home. (c) Standard: Support services.	***Add to 1i***: "Periodic monitoring of the patient's home adaptation, including at minimum an annual visit to the patient's home by all facility personnel if geographically feasible (RN, social worker, dietitian, and machine technician) in accordance with the patient's plan of care." ***Rationale***: Members of the interdisciplinary team can offer better care to patients after seeing the patient in his/her home environment where they can observe barriers and supports first-hand. The members should be specified to ensure equal visitation of the team members across all dialysis units. The language of this part of the proposed conditions is vague and subject to varying interpretation (i.e. exactly who are the "facility personnel" who will visit the patient's home?) ***Add to 1iv***: "Patient consultation with all members of the interdisciplinary team, as needed." ***Rationale***: The language of this part of the proposed conditions is vague and subject to varying interpretation
NEWCONDITION Staff assisted skilled nursing home dialysis	***Add***: A new condition for dialysis provided in a nursing home setting (that is not incorporated into the "home" condition 494.100) ***Rationale***: Nursing home dialysis is typically provided by staff. Home dialysis (PD or home hemodialysis) is typically performed by a trained patient and/or a helper. Making these treatments equivalent obscures important differences between them, including the staff training/supervisory needs of nursing home dialysis patients. To include care in a nursing facility/skilled nursing facility (NF/SNF) under "care at home" is inappropriate. There is a tremendous difference in what CMS must do to protect the health and safety of highly functioning, trained patients who do self-care at home (or have assistance from a trained helper at home) and patients who require personnel in an NF/SNF to perform dialysis because they are too debilitated to travel to a dialysis facility. ***Reference:***□Tong & Nissenson, 2002 ***Add:*** Language to this proposed condition that would mandate " A Nursing facility/Skilled Nursing Facility providing full-care dialysis to residents with ESRD, must be certified as a dialysis facility and comply with all sections of this rule, including personnel qualifications." ***Rationale***: Patients receiving dialysis in NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility, including consultation with a qualified nephrology social worker. While NFs and SNFs may employ social workers, these social workers may not hold a master's degree and will not have the specialized knowledge of the complex social and emotional factors affecting the dialysis patient. To ensure that the health and safety of NF or SNF hemodialysis patients is protected, any proposed requirements should specifically incorporate Secs 494.70, 494.80 and 494.90 of

	the proposed conditions of coverage.
§494.110 Condition Quality assessment and performance improvement. (a) Standard: Program scope.	***Add***: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental, and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors." ***Rationale***: To ensure patient-centered care, patient functioning and well-being must be one of the quality indicators that is monitored and improved. ***Add***: (2)(new iii) "Psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality. ***Add***: (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form" ***Rationale***: These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes. ***Comment:*** CNSW agrees that dialysis providers must measure patient satisfaction and grievances. CNSW supports the use of a standardized survey (such as the one being currently developed by CMS) for measuring patients' experience and ratings of their care. Such a survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that can be used for public reporting and monitoring purposes. The survey should be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.
494.140 Condition Personnel qualifications	***Comment:*** CNSW recommends that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is

	time spent assessing and counseling patients. • Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs. This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. For all of these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).
494.140 Condition Personnel qualifications (d) Standard: Social worker.	***Change the language of d to***: *Social worker.* The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks. ***Rationale & References***: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree.

We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription

issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003).

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.

494.140 Condition Personnel qualifications

Add: (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage.

Rationale & References: We agree with the preamble that dialysis patients need essential social services

including transportation, transient arrangements and billing/insurance issues. We also firmly agree with the preamble that these tasks should not be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is-adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education. In the Promoting Excellence in End-of-Life Care's 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, workgroup members recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, taking 9% of their time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination periods.
- 44% of social workers were primarily responsible for completing admission packets.
- 18% of social workers were involved in collecting fees from patients. Respondents noted that this could significantly diminish therapeutic relationships and decrease trust.
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent counseling and assessing patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs.

This evidence clearly demonstrates that there needs to be another team member who can handle these clerical social service needs. This position would be cost-effective, as the person in this role can help

	patients obtain insurance coverage for dialysis that they normally would not have and increase facility's reimbursement. As discussed and referenced below in detail, CNSW recommends a ratio of 75 patients per full-time equivalent social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing). Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients. In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients

	are being denied access to quality social work services' (p.59). Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios): • Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence. • Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression. Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
§**494.180 Condition** Governance. (b4) Standard. Adequate number of qualified and trained staff.	***Comment:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.
§**494.180 Condition** Governance. (b5) Standard. Adequate number of	***Add (5ix):*** Add "Psychosocial issues related to ESRD and its treatment regimes, as provided by the facility social worker." ***Comment:*** Technicians have the most contact with patients and need to be attuned to patients'

Adequate number of qualified and trained staff.	psychosocial issues so as to most effectively collaborate with the social worker and achieve patient outcomes.
§**494.180 Condition** Governance. (h) Standard: Furnishing data and information for ESRD program administration.	(h) Standard: Furnishing data and information for ESRD program administration. ***Add***: (3)(new iv) "Annual reporting of facility aggregate functioning and well-being (physical component summary scores and mental component summary scores) and vocational rehabilitation status according to categories on the CMS 2728 form." ***Rationale***: These data would be easy to collect, would permit comparisons between clinics, and would serve as a basis for QAPI.

REFERENCES

ADA, Title III, Part 36, Subpart A, Section 36.303, auxiliary aids (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-97857)

ADA Title III, Part 36, Subpart A, Section 36.304, removal of barriers (http://www.usdoj.gov/crt/ada/reg3a.html#Anchor-91481)

Anderson, R. (1986). The CSWE Accrediting Standards for Social Work Education. *Social Work in Education*. CCC Code: 0162-7961/86.

Andreucci, V. E., et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) data on medications in hemodialysis patients. *Am J Kidney Dis*. 44(5 Suppl 3):61-7, 2004.

Auslander, G. K., Buchs, A. (2002). Evaluating an activity intervention with hemodialysis patients in Israel. Social Work Health Care. 35(1-2):407-23.

Auslander, G., Dobrof, J., & Epstein, I. (2001). Comparing social work's role in renal dialysis in Israel and the United States: the practice-based research potential of available clinical information. *Social Work in Health Care*, 33(3/4), 129-151.

Beder, J. (1999). Evaluation research on the effectiveness of social work intervention on dialysis patients: the first three months. *Social Work in Health Care*, 30(1), 15-30.

Beder, J., Mason, S., Johnstone, S., Callahan, M. B., & LeSage, L. (2003). Effectiveness of a social work psychoeductional program in improving adherence behavior associated with risk of CVD in ESRD patients. *Journal of Nephrology Social Work*, 22, 12-22.

Blake C, Codd MB, Cassidy A, O'Meara YM. Physical function, employment and quality of life in end-stage renal disease. *J Nephrol.* 13(2):142-9, 2000.

Bogatz, S., Colasanto, R., & Sweeney, L. (2005). Defining the impact of high patient/staff ratios on dialysis social workers. *Nephrology News & Issues*, Jan, 55-60.

Bonner, C., Dean, R., & Greenspan, R. (1989) Standards for Practice: The Development of the Clinical Social Worker in the First Two Years. *The Clinical Supervisor* 1989. 7(4), 31-45.

Booz, A., & Hamilton, Inc. (1987) *The Maryland Social Work Services Job Analysis and Personnel Qualifications Study*. Prepared for the Department of Human Resources State of Maryland

Burrows-Hudson, S. (1995). Mortality, morbidity, adequacy of treatment, and quality of life. *ANNA Journal*, 22(2), 113-121.

Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M. (1998). Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. *Journal of Nephrology Social Work*, 18, 66-79.

Callahan, M. B., Witten, B., & Johnstone, S. (1997). Improving quality of care and social work outcomes in dialysis. *Nephrology News & Issues*, 2(4), 42-43.

Chang, C. F., Winsett, R. P., Gaber, A. O., & Hathaway, D. K. (2004) Cost-effectiveness of post-transplantation quality of life intervention among kidney recipients, *Clinical Transplantation*, 18(4), 407-415.

Coulton, C. (1979). A study of the person-environment fit among the chronically ill. *Social Work in Health Care*, 5(1), 5-17.

Council on Social Work Education: Commission on Accreditation, *Handbook of Accreditation Standards and Procedures* (Fourth Edition). Subsection B5.7.9 and M5.7.11 and Subsection B5.7.7 and M5.7.8, pp. 99, 137.

Curtin RB, Oberley ET, Sacksteder P, Friedman A. (1996). Differences between employed and nonemployed dialysis patients. *Am J Kidney Dis.* 27(4):533-40.

Curtin RB, Mapes DL. (2001) Health care management strategies of long-term dialysis survivors.*Neph Nurs J.* 28(4):385-394.

Curtin RB, Bultman DC, Schatell D, Chewning BA. (2004) Self-management, knowledge, andfunctioning and well-being of patients on hemodialysis. *Neph Nurs J* 31(4):378-387.

Curtin RB, Bultman DC, Thomas-Hawkins C, Walters BA, Schatell D. Hemodialysis patients' symptom experiences: effects on physical and mental functioning. *Nephrol Nurs J.*;29(6):562, 567-74; discussion 575, 598, 2002.

Curtin RB, Klag MJ, Bultman DC, Schatell D. Renal rehabilitation and improved patient outcomes in Texas dialysis facilities. Am J Kidney Dis.;40(2):331-8, 2002.

Curtin RB, Sitter DC, Schatell D, Chewning BA. Self-management, knowledge, and functioning and well-being of patients on hemodialysis. *Nephrol Nurs J* 31(4):378-86, 396; quiz 387, 2004.

DeOreo, P. B. (1997). Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *American Journal of Kidney Diseases*. 30(2), 204-212.

Devins, G. M., Mandin, H., Hons, R. B., Burgess, E. D., Klassen, J., Taub, K., Schorr, S., Letourneau, P. K., & Buckle, S. (1990), Illness intrusiveness and quality of life in end-stage renal disease: comparison and stability across treatment modalities. *Health Psychology*, 9(2), 117-142.

Dhooper, S., Royse, D., & Wolfe, L. (1990) Does social work education make a difference? *Social Work Education,* 1990, 35 (1), 57-61.

Dobrof, J., Dolinko, A., Lichtiger, E., Uribarri, J., & Epstein, I. (2001) Dialysis patient characteristics and outcomes: the complexity of social work practice with end-stage renal; disease population. *Social Work in Health Care*, 33, 105-128.

Forum of ESRD Networks. *Designing a Collaborative Action Plan with ESRD Stakeholders,* 2003. (http://www.esrdnetworks.org/DPPCFinalReport.pdf)

Frank, A., Auslander, G. K., & Weissgarten, J. (2003). Quality of life of patients with end-stage renal disease at various stages of the illness. *Social Work in Health Care*, 38(2), 1-27.

Gudes, C. M. (1995). Health-related quality of life in end-stage renal failure. *Quality of Life* ESRD Network of Texas (2002). Social Services Practice Recommendations. *http://www.esrdnetwork.org/professional_standards.htm*

Holley, J. L., Barrington, K., Kohn, J., & Hayes, I. (1991). Patient factors and the influence of nephrologists, social workers, and nurses on patient decisions to choose continuous peritoneal dialysis. *Advances in Peritoneal Dialysis*, 7, 108-110.

Johnstone, S. (2003). Evaluating the impact of a physical rehabilitation program for dialysis patients. *Journal of Nephrology Social Work*, 22, 28-30.

Johnstone, S. & Halshaw, D. (2003) Making peace with fluid social workers lead cognitive-behavioral intervention to reduce health-risk behavior. *Nephrology News & Issues* (12), 20-31.

Johnstone, S., Seamon, V. J., Halshaw, D., Molinair, J., & Longknife, K. (1997). The use of medication to manage patient-staff conflict in the dialysis clinic. *Advances in Renal Replacement Therapy*, 4(4), 359-371.

Johnstone, S., Walrath, L., Wohlwend, V., & Thompson, C. (2004). Overcoming early learning barriers in hemodialysis patients: the use of screening and educational reinforcement to improve treatment outcomes. *Advances in Chronic Kidney Disease*, 11(2), 210-216.

Juhnke, J & Curtin, R.B. (2000) New study identifies ESRD patient education needs. *Nephrology News & Issues*14(6):38-9.

Kalantar-Zadeh, K., Kopple, J. D., Block, G., & Humphreys, M. H. (2001). Association among SF36 quality-of-life measures and nutrition, hospitalization, and mortality in hemodialysis. *Journal of the American Society of Nephrology*, 12, 2797-2806.

Kaitelidou, D., Maniadakis, N., Liaropouls, L., Ziroyanis, P., Theodorou, M., & Siskou, O. (2005). Implications of hemodialysis treatment on employment patterns and everyday life of patients. *Dialysis & Transplantation*, 34(3), 138-147, 185.

Katon, W., & Schulberg, H. (1997). Epidemiology of depression in primary care. *General Hospital Psychiatry,*14, 237-247.

Kaveh K & Kimmel PL. (2001). Compliance in hemodialysis patients: multidimensional measures in search of a gold standard. *American Journal of Kidney Diseases* 37(2):244-66.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D., Verne, D., Alleyne, S., & Cruz, I. Veis, J (2000). Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International*, 5(10), 2093-2098.

Kimmel, P., Peterson, R., Weihs, K., Simmens, Alleyne, S., Cruz, I., & Veis, J (1998). Psychosocial factors, behavioral compliance and survival in urban hemodialysis patients. *Kidney International*, 54, 245-254.

□Kimmel PL et al Survival in hemodialysis patients: the role of depression. *J Am Soc Nephrol.* 4(1):12-27, 1993.

King K, Moss AH. The frequency and significance of the "difficult" patient: The nephrology community's perceptions. *Adv Chronic Kidney Dis*. 2004 Apr;11(2):234-9.

Knight EL et al. The association between mental health, physical function, and hemodialysis mortality. *Kidney Int.* 63(5):1843-51 2003.

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 41(11):1284-92, 2003.

Kutner NL et al. Functional impairment, depression, and life satisfaction among older hemodialysis patients and age-matched controls: a prospective study. *Arch Phys Med Rehabil.* 81(4):453-9, 2000.

Levenson, J., & Olbrisch, M. (2000). Psychosocial screening and candidate selection. In P. Trzepacz & A. DiMartini (Eds.), *The transplant patient: biological, psychiatric, and ethical issues in organ transplantation* (pp. 21-41). Cambridge: Cambridge University Press.

Lowrie EG, Curtin RB, LePain N, Schatell D. Medical outcomes study short form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. *Am J Kidney Dis*. 41(6):1286-92, 2003.

Mapes, D., Bragg-Gresham, J. L. Bommer, J. Fukuhara, S., McKevitt, P., & Wikstrom, B (2004). Health-related quality of life in the dialysis outcomes and practice patterns Study (DOPPS) American Journal of Kidney Diseases, 44 suppl(5), 54-60.

Mayo K. (1999)Can evening dialysis services improve the chances of rehabilitation? A Network #7 study. *Nephrol News Issues*. 13(6):37-8.

McKinley, M., & Callahan, M.B. (1998). Utilizing the case management skills of the nephrology social worker in a managed care environment. In National Kidney

Foundation (Ed.), *Standards of practice for nephrology social work, 4th ed,* (pp. 120-128). NY: National Kidney Foundation.

McLaughlin K, Manns B, Mortis G, Hons R, Taub K. (2003). Why patients with ESRD do not select self-care dialysis as a treatment option. *Am J Kidney Dis.* 41(2):380-5.

Merighi, J. R., & Ehlebracht, K. (2005). Emotional Exhaustion and Workload Demands in Renal Social Work Practice, *Journal of Nephrology Social Work*, 24, 14-20, *Journal of Nephrology Social Work*, in press

Merighi, J. R., & Ehlebracht, K. (2004a). Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. *Nephrology News & Issues*, 18(4), 58-63.

Merighi, J. R., & Ehlebracht, K. (2004b). Issues for renal social workers in dialysis clinics in the United States. *Nephrology News & Issues*, 18(5), 67-73.

Merighi, J. R., & Ehlebracht, K. (2004c). Unit-based patient services and supportive counseling. *Nephrology News & Issues*, 18(6), 55-60.

Morrow-Howell, N. (1992). Clinical case management: the hallmark of gerontological social work. *Geriatric Social Work Education*, 18, 119-131.

National Association of Social Workers (1981) *Standards for the classification of social work practice.* Maryland: National Association of Social Workers.

Promoting Excellence in End-of-Life Care (2002), *End-Stage Renal Disease Workgroup Recommendations to the Field,* Missoula, MT: The Robert Wood Johnson *Protecting the Privacy of Patients' Health Information* (http://www.hhs.gov/news/facts/privacy.html)

Rasgon SA, Chemleski BL, Ho S, Widrow L, Yeoh HH, Schwankovsky L, Idroos M, Reddy CR, Agudelo-Dee L, James-Rogers A, Butts E. (1996). Benefits of a multidisciplinary predialysis program in maintaining employment among patients on home dialysis. *Adv Perit Dial.* 12:132-5.

Rabin, P. L. (1983). Psychiatric aspects of end-stage renal disease: diagnosis and management. In W. J. Stone & P. L. Rabin (Eds.) *End-Stage renal disease: an integrated approach, (*pp. 111-147). NY: Academic Press.

Rasgon, S., Schwankovsky, L., James-Rogers, A., Widrow, L., Glick, J., & Butts, E. (1993). An intervention for employment maintainence among blue-collar workers with end-stage renal disease. *American Journal of Kidney Diseases*, 22(3), 403-412.

Rau-Foster M. The dialysis facility's rights, responsibilities, and duties when there is conflict with family members. *Nephrol News Issues.* 15(5):12-4, 2001.

Renal Physicians Association and American Society of Nephrology. *Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis*

Rosen, L. S. (1999). Common psychosocial factors in the treatment of end stage renal disease. *Journal of Nephrology Social Work*, 19, 69-72.

Russo, R. (2002). The role of the renal social worker in the 21st century. *Nephrology News & Issues*, 16(3), 38,40.

Rubin, H., Jenckes, M., Fink, N., Meyer, K., Wu, A., Bass, E., Levin, N., & Powe, N. (1997). Patient's view of dialysis care: development of a taxonomy and rating of importance of different aspects of care. *American Journal of Kidney Disease*, 30(6), 793-801.

Siegal, B., Witten, B., Lundin, A.P (1994). Patient access and expectations of nephrology social workers. *Nephrology News and Issues*, April, 32-33,40.

Sikon, G. M. (2000). Pre-dialysis education reduces anxiety in the newly diagnosed chronic renal failure patient. *Dialysis & Transplantation*, 6, 346, 344-345.

Tong E. M. & Nissenson, A. R. (2002). Dialysis in nursing homes. *Seminars in Dialysis*. 15(2):103-6.

Vourlekis, B., & Rivera-Mizzoni, R. (1997). Psychosocial problem assessment and ESRD patient outcomes. *Advanmces in Renal Replacement Therapy*, 4(2), 136-144.

Wallace, S., Goldberg, R., & Slaby, A. (1984). *Guide for clinical social work in health care*. NY: Praeger Publishers.Witten B, Howell P, Latos D. (1999). Improving employment outcomes: the renal care team's role. *Nephrol News Issues*. 13(3):46-8.

Witten B, Schatell DR, Becker BN. Relationship of ESRD working-age patient employment to treatment modality. (Abstract) *J Am Soc Nephrol*. 2004; 15:633A.

Wuerth D, Finklestein SH, Finklestein FO. The identification and treatment of depression in patients maintained on dialysis. *Semin Dial*. 18(2):142-6, 2005.